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GRIFFITH COLLEGE

**ENHANCING QUALITY RISK MANAGEMENT IN IRISH LIFE
SCIENCES THROUGH BIG DATA ANALYTICS: A STRATEGIC
ANALYSIS**

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DECLARATION

I, Nandhana Padmakumar, declare that the dissertation entitled, Enhancing quality risk management in Irish life sciences through big data analytics: A strategic analysis, submitted in partial fulfilment of the requirements to the award of MSc in Digital Transformation, is my own individual work. All the used information and data were properly cited and referenced with reference to existing academic standards.

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24/08/2025

ACKNOWLEDGEMENT

To begin with, I would like to thank the Almighty God for the endless blessings, guidance, and strength during this period of study. His grace has been my source for the strength, courage, determination, and perseverance to complete the dissertation.

I am immensely thankful to my supervisor, Nicola Rice, who has been most helpful through her valuable advice, useful comments, and constant encouragement. Her knowledge and support have been valuable in the development of this research and quality in the research.

I also want to express my sincere gratitude to the faculty and staff of Digital Transformation Department at Innopharma Education and Griffith College Dublin. They have mentored me and encouraged me to pursue this research through the knowledge and expertise they have shared with me.

I would like to thank all the industry professionals, quality and regulatory, digital transformation, production and manufacturing and data analytics experts who took part in my survey and contributed their time and expertise to it. Your efforts made a notable contribution to the contents and the quality of this dissertation.

I am eternally grateful to my family for their constant prayers, unconditional love and belief in me. Your encouragement has been the greatest strength and motivation to me.

I would also like to express my gratitude to my classmates and peers who have helped me, offered useful feedback, and supported the research. Your support and companionship have made this more worthy.

Finally, I would like to thank everyone who supported and encouraged me in one way or the other during this dissertation.

Nandhana Padmakumar

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LIST OF ABBREVIATIONS

BDA	- Big Data Analysis
QRM	- Quality Risk Management
EMA	- European Medicines Agency
HPRA	- Health Products Regulatory Authority
GDP	- Gross Domestic Product
FDA	- Food and Drug Administration
ML	- Machine Learning
TAM	- Technology Acceptance Model
CMO	- Contract Manufacturing Organizations
CRO	- Contract Research Organizations
FMEA	- Failure Mode and Effective Analysis
HACCP	- Hazard Analysis and Critical Control Points
CAPA	- Corrective and Preventive Actions
QA	- Quality Assurance
GDPR	- General Data Protection Regulation
GAMP	- Good Automated Manufacturing Practice
TAM	- Technology Acceptance Model
PU	- Perceived Usefulness
PEOU	- Perceived Ease of Use
DDDM	- Data-Driven Decision-Making
STS	- Social-Technical System Theory

ABSTRACT

The Irish life sciences sector has consistently been a leading producer of pharmaceuticals and biotechnology products and is now facing pressure to digitally transform its approach to Quality Risk Management (QRM). This dissertation has described how Big Data Analytics (BDA) can help in improving QRM to enable predictive modelling, real-time monitoring and data-driven decision-making under the systems of ICH Q9. A positivist philosophy, and deductive methodology were used to gather the primary data through an online survey of 109 industry professionals, 103 valid responses were used to analyse variables using descriptive and inferential statistics.

The findings show that although more than 60 percent of the organisations have started implementing BDA, maturity level and integration is not high due to legacy systems, regulatory and complexity and skills gaps in the workforce. However, companies who have implemented BDA already see tremendous benefits such as reduced deviations, faster batch release, audit preparedness and reductions in cost. Statistical results identify digital maturity, good data governance and competency of the employees as key factors that facilitate success with BDA-driven QRM. The dissertation presents concluding comments and recommendations to the Irish life sciences organisations including a recommendation to the organisation regarding investment in digital infrastructure, skills, and well developed governance frameworks that would ensure that the organisation complies with the regulations as well as be competitive in the long-term.

This study can contribute to the academic debate on the digital transformation within the life sciences sector and serve as a practical guide to industry leaders and policymakers interested in making the highly regulated Irish life science environment, including the pharmaceutical and bio sector, more competitive and compliant.

Nandhana Padmakumar

CHAPTER 1: INTRODUCTION

1.1 Purpose of the study

This study aims at realizing how Big Data Analytics (BDA) techniques can be used to improve Quality Risk Management (QRM) in Irish life sciences companies by detecting deviation indicators, reinforcing control and enabling judgmental decision-making. The primary objective is to consider an application of data related approaches such as machine learning, data lakes and visual analytics in QRM frameworks including ICH Q9.

1.2 Context of the study

The Irish Life science industry is one of the major parts of the global pharmaceutical and biotechnology industry, which contributes to the economy and employment of Ireland. More than 85 pharmaceutical companies are in Ireland and nine of the ten largest companies in the world. These companies are set up under the regulatory bodies such as European Medicines Agency (EMA), Health Products Regulatory Authority (HPRA) and the U.S Food and Drug Administration (FDA). Quality, safety and compliance are crucial to this industry as it is very important for the patient health, sustainability of the business and access to the markets. QRM is central to this regulatory ecosystem but has historically relied on retrospective, paper-based methods, often subjective and slow to adapt. These methods tend to be slow and inaccurate to the current fast and dynamic manufacturing processes (ICH, 2023).

The development of digital transformation especially in the context of Industry 4.0 offers the chance to reinvent QRM by incorporating BDA. BDA including predictive modelling, Machine Learning (ML), data visualization, real-time monitoring provides the potential to transform functions of QRM beyond being a reactive, compliance driven process to a proactive, predictive, adaptive process (Mazzuto and Ciarapica, 2019). This is a digital innovation that has the potential to change QRM by shifting it into a strategic tool, providing real-time risk detection and predictive modeling as well as an improved decision-making system. It involves the applications of technologies like Machine learning, artificial intelligence, cloud computing and processing of real-time data to analyze large and diverse data (O'Mahony *et al.*, 2024).

With its worldwide pharmaceutical and biotechnological production, Ireland is empowered to make this transition. But there are several companies, particularly smaller biotech companies still use the traditional approaches to QRM and experience systematic difficulties in implementing BDA. This sets an urgent necessity to explore the existing BDA utilization in

QRM, its advantage and the possible ways to resolve the issues of implementation in the context of Ireland.

1.3 Rationale for the topic selection

The reason behind this research lies in the fact that there is an unmet gap involving technologies and practice in the Irish life sciences sector. Although BDA has been found practical in most industrial contexts, it has not been thoroughly studied in QRM within the life sciences (particularly in Ireland) and so it can only be used to an extent. It is unspecified how BDA tools can support regulatory demands, and most of the organizations are not sufficiently prepared to incorporate digital capabilities to the old systems and processes. The necessity of digital adaptation has been emphasized by the COVID-19 epidemic, with remote auditing, real-time monitoring and access to data becoming operation essentials. All these underlined the presence of resilient and adaptive QRM systems, but with advanced analytics (Brown, 2021).

The absence of Irish-specific literature makes it difficult to know the level of digital maturity within the industry, the regulatory and organisational obstacles to adoption of the BDA, and the approach that may support a successful integration.

1.4 Significance and Justification of study

The significance of the present research is in its relation to one of the most complicated regulated and technologically advancing environments. QRM is a compulsory factor of all life science processes, and its modernization, which is possible through BDA can become a source of significant efficiency gains, increased quality of produced products and compliance. In the Pharma 4.0 context, there is an increasingly present pressure on companies to focus on improving their digital maturity, where BDA is a core component of that evolution. Although this is extensively discussed both theoretically, a significant gap in the empirical literature can be identified in terms of the actual implementation of BDA into QRM, especially within the Irish life sciences industry (Dong *et al.*, 2023). It is important to bridge this gap because, when used properly, BDA will not only save money and limit regulatory risk but also allow faster and better-informed decisions to give companies a competitive edge. Moreover, as regulators give greater attention to data integrity and traceability, other organizations lagging in digital innovation run major risks of non-compliance, and disruption of their operations. This research will contribute to the academic knowledge on digital quality systems and provide

recommendations that can be used by industry professionals, regulators, and decision makers of the Irish life sciences companies.

1.5 Research Questions

1. How far have concepts of Big Data Analytics been implemented in the practice of QRM in Irish life sciences companies?
2. What are the benefits of BDA integration?
3. What are the key technological, organizational and regulatory obstacles to successful implementation of BDA in QRM?
4. What is the role of the digital maturity, data governance and employee competency in ensuring the success of BDA-assisted QRM systems?
5. What are the strategic measures that can help transform the complaint and efficient use of BDA in QRM models?

1.6 Structure of the dissertation

The dissertation is structured in five main chapters.

- Chapter 1 is the introduction of the research by outlining the background, purpose and context of the study, the rationale for the topic, research questions and significance of the study.
- Chapter 2 presents a complete overview of the Big Data Analytics, Quality Risk Management, technology adoption framework, as well as of the associated barriers and enablers
- Chapter 3 will provide a description of the research methodology, sampling strategy, the data collection tools, and the methods of data analysis.
- Chapter 4 presents the findings of the survey are provided and analyzed with the help of descriptive and inferential statistics.
- Chapter 5 presents the summary of the key findings, strategic recommendations, the limitations of the study and the suggestions towards future research work.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

This chapter presents the critical review of the existing literatures concerning the research topic, which addresses the application of BDA and QRM in the Irish life sciences sector. It creates the knowledge and applied background by analysing the critical concepts, business implementation, and theoretical foundations that can be used to introduce BDA into risk management practice. The literature is structured analytically to be consistent with the aims of the study and is classified into four main themes: the place of BDA in life sciences, the fundamentals of QRM to BDA, the alignment of BDA and QRM-based frameworks such as ICH Q9, and the strategic issues and possibilities presented by this shift.

Based on the results of the empirical review, the chapter presents applicable theories and models of the Technology Acceptance Model (TAM), ISO 31000/ICH Q9 risk frameworks, Data-Driven Decision-Making theory, and Socio-Technical Systems theory. Such theoretical orientations provide some answers to how organisations embrace and implement data-driven instruments in overly controlled assumptions. Then a conceptual framework is created which graphically illustrates the important variables and the relationships between them, and forms a guide to empirical research. The chapter ends with a recognition of literature gaps and the rationale of undertaking a study based on the unavailability of specific studies identifying the regulated environment of the life sciences in the Irish context.

2.2 Empirical Study

2.2.1 Concept of Big Data Analytics (BDA) in the Life Science Sector

BDA has become one of the most revolutionary phenomena in the life sciences industry globally, making data-driven decisions and real-time risk monitoring to speed up the innovation process. In Ireland, where the activity of pharmaceutical and biopharmaceutical production is a significant source of national GDP, BDA will have a special value in the improvement of quality, regulatory compliance, and efficiency of processes (Clancy and O'Rourke, 2021). The subsidiaries of international companies (such as Pfizer, Johnson & Johnson, and Takeda) that are headquartered in Ireland have already started using BDA tools to monitor the processes and provide predictive maintenance in real-time (IDA Ireland, 2022). But even after technological advancement, diffusion has been irregular in the industry because of organisational, regulatory, and infrastructural challenges.

The BDA in life sciences refers mainly to acquiring and processing high volume, high velocity and high variety of data sources, and it includes clinical trials, manufacturing systems, quality logs and customer complaints. According to the findings provided by Wang *et al.*, (2018) , BDA contributes to the exhibition of quality deviations and adverse events that have been shown to lead to regulatory violations and product recalls before their occurrence. This is especially applicable for Ireland, wherein the regulation in the European Medicines Agency (EMA) and the FDA regulatory compliance is highly important because Ireland is an exporter of certain substances internationally. Visual analytics and dashboards used in the process contribute to determining the trends and risks of all product lifecycle phases (Batko and Ślęzak, 2022).

Machine learning (ML) algorithms are a particular group of BDA that is progressing in the field of pharmaceutical quality control. Luo *et al.*, (2024) found that ML models can perform pattern recognition and anomaly detection in production settings, which also helps QRM by causing a reduction of human errors and bias. Pharmaceutical companies in Ireland that embrace the Good Manufacturing Practice (GMP) are using supervised approaches to learning to make predictions about either deviations or determine the failures(Yang *et al.*, 2020). However, It fails to demonstrate the organisational incompetency to integrate the latter instruments into the recognised QRM systems that include ICH Q9 without breaching the data integrity principles.

The second thing that is coming into focus is the concept of using data lakes to gather multiple data sets in a single collection, where such data sets can be accessed by cross functional teams when they engage in collaborating on quality and compliance projects. The increasing accessibility and flexibility to downstream analytics using data lakes are also pinpointed by Hashem *et al.*, (2015). This capability has particular applicability in the Irish life sciences sector amongst Contract Manufacturing Organisations (CMOs) and Contract Research Organisations (CROs), which must manage multiple sites. Nonetheless, data lake limitation on data governance, standardisation, and privacy remains a challenge that constrains the adoption of these data lakes (Khan *et al.*, 2014)

In spite of the extensive opportunities in the sphere of efficiency and innovation offered by BDA, essential worries connected with the ethical usage of information, especially when dealing with combined patient, clinical, and production data in analytics tools, exist. According to (Timan and Mann, 2021), regulatory frameworks safeguarding the privacy of data, like GDPR, have taken a decisive role in the determination of BDA strategies in Europe, including Ireland. Thus, it is not sufficient that life sciences companies seek technological resolutions,

but also accumulate powerful data governance strategies within a company to make them regulation compliant.

2.2.2 Quality Risk Management (QRM) in the Life Science Sector

QRM is a systematic process of mapping, assessing as well and managing risks to quality in the entire pharmaceutical life cycle. It has now become very important in the life sciences industry, especially with regulations like ICH Q9 that are encouraging a proactive and science-based approach(Wagh and Darde, 2025). The pharmaceutical industry and Irish life sciences industry have become increasingly aligned with QRM in order to control variability in operations, regulatory requirements, and the safety of patients (Milá Cáceres, 2010).

ICH Q9 guideline has been recognised as the foundation of pharmaceutical QRM, which holds the standardised evaluation of the chance and the severity of potential quality failures. According to Poli *et al.*, (2024), ICH Q9 combines hazard assessment, hazard control, communication of all hazards and reviews of all hazards into a flexible tool that can be applied in many quality processes. An example of applying QRM is in Ireland, where multiple pharmaceutical companies can reach the international market; QRM plays a pivotal role in remaining in line with the EU and FDA regulations (Madigan, 2020) . However, critics indicate that QRM has acquired the well-developed principles, but they are not always applied in practice because of the absence of a risk culture and a failure to integrate well with the real-time information(Reddy *et al.*, 2014).

Analysis Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), and risk ranking matrices have been the main tools used in traditional QRM practices. These instruments, despite being useful, are usually qualitative and subjective, and it is possible that inconsistencies in decision-making occur(Bais and Rathod, 2024). Heavy dependence on human knowledge and historical evidence restricts the predictive ability of QRM, particularly in manufacturing facilities that are complex in nature. It is due to these aspects that professionals have discussed the importance of implementing data-related methods and in-depth surveillance tool kits to achieve a higher predictability and control of risks (Mulholland, 2024).

Moreover, QRM requires organisational and technological issues in the Irish life sciences firms. A report by BioPharmaChem Ireland (2022) showed that most of the big companies have established formality in their QRM policies, but there was usually a gap between corporate risk approaches and how they are implemented at the manufacturing plant(Ismael and Ahmed, 2020). Such a void is further worsened by the unavailability of real-time visibility of quality

information, which means that risks are not identified and addressed in time. In support of this issue, the study by Deidda (2018) indicates that organisations with a composed system of digital QRM demonstrate a better performance in the management of deviations, CAPAs (Corrective and Preventive Actions), as well as readiness in an audit.

Digital transformation can play an important role in materially improving QRM capabilities with the aspect of real-time and dynamic insights and the ability to deliver predictive actions. However, as Jain (2022) mentions, the majority of QRM systems are reactive, and their most important parts are designed to analyse what has already happened, instead of preventing. The integration of Big Data tools into QRM, in particular, in ICH Q9 contexts, may help to fill this gap to enable more detailed data-driven decision-making processes.

2.2.3 Integration of Big Data Analytics and Quality Risk Management

The combination of BDA with QRM is a step in the progressive development of pharmaceutical and life sciences companies and allows data-driven quality management, which is predictive and real-time. However, traditional QRM frameworks, though sufficiently powerful, frequently do not have the capabilities to operate on large-scale and mixed data sets (Khatib *et al.*, 2023). Machine learning (ML), natural language processing (NLP), data lakes, and visual analytics are some of the tools of Big Data that can be used to complement the existing ICH Q9-based systems with additional capabilities that include: strengthening risk-identification processes, allowing continuous monitoring, and better decision-making (Rane *et al.*, 2024).

BDA assists in identifying process drifts and out-of-specification results quickly, as well as future compliance failures to be indexed and discovered through real-time monitoring and predictive modelling. With ML models, as it has been suggested by Ren *et al.*, (2019), the manufacturers can find patterns in deviations and adverse event reports proactively that will facilitate a more specific and timely mitigation of risks. The shift towards proactive risk management is also effective in Good Manufacturing Practice (GMP) environments that have poor product safety and standards that may be not able to gain a place in the market. This statement is further made by (Al-Zaiti *et al.*, 2022), who emphasises the role of ML-based analytics in minimising the element of human bias in the quality appraisals, moving towards a high level of consistency in the process of deviation classification.

The centralised platforms and data lakes are critical in this integration as they aggregate both the structured and unstructured data that is available in many sources, including batch records, quality control outcomes, equipment sensors and clinical databases. Hashem *et al.*, (2015) also state that cross-functional teams can conduct enhanced analytics with the help of data lakes,

and this can enhance risk assessment precision. Practically, the firms in the pharmaceutical industry in Ireland that have gone global stand a lot to gain because of such integration, and they have the chance of making local manufacturing plants to realign with the quality standards being attained internationally, courtesy of the insights in analytics (Van Egeraat and Barry, 2008).

One more important tool, which connects BDA and QRM with each other, is visual analytics. Such tools are based on dashboards, heatmaps, and trend graphs that help to demonstrate complicated information easily and conveniently and make the process of decision-making more rapid, judgmental Zhao *et al.*, (2016). Visual analytics helps in the phases of risk communication and review in ICH Q9 because it enables the stakeholders to discuss risk priorities and control strategies. It is especially applicable in the Irish life sciences companies working in the environment of a complex supply chain in which real-time visual awareness enhances operational and regulatory agility (IDA Ireland, 2022).

Nonetheless, without challenges, integration is impossible. One of them is the incompatibility between the conventional QRM procedures and the new data governance paradigms under discussion in this study (Lopes *et al.*, 2022) . There is high regulatory pressure to adopt data integrity, traceability, and validation that should be strictly maintained by regulatory bodies like EMA, FDA, when using complex analytics algorithms in use. Wang *et al.*, (2018) present the fact that organisational culture, outdated IT set-ups and skills gaps are the usual obstacles to the smooth application of BDA in quality systems. As an example, numerous Quality Assurance (QA) individuals learn compliance and documentation techniques practices rather than advanced data science skills, creating a block to integration.

Although these barriers still exist, the current industry trends indicate a drift towards digital quality ecosystems. Yang *et al.*, (2020) report shows that the stakeholders in the Irish life sciences are now focusing on integrated QRM-BDA platforms in their Industry 4.0 plans. These platforms integrate QRM with the concepts of digital twins, real-time control loops and advanced analytics to produce a completely digitalised quality environment. Deshmukh (2022) explained that reduced time of handling deviations, improved resource distribution, and overall stronger quality management are the outcomes of such integration.

Also, BDA integration in QRM is consistent with the current updating of the ICH Q9 (R2), which focuses on risk-based strategies and better communication about the risk with better tools. This is because firms should consider more data-centric technologies as part of their evolution to take yet another step in shifting QRM practices beyond procedural activities to quality and innovation enablers (ICH, 2023). At the Irish level, the importance of the

concurring aspect of these revisions is to go with regulatory compliance as well as global competitiveness.

2.2.4 Challenges and Opportunities

The integration of BDA in QRM in the life sciences industry has great potential in transformational value, although it also comes with diversity and complexity of strategic, technical, and regulatory issues (Sivarajah *et al.*, 2017). Understanding these challenges and opportunities is highly relevant to firms that operate in Irish life sciences as part of an effort to streamline operations at the quality functions and stay competitive internationally.

Among the utmost obstacles, there is the absence of digital maturity and infrastructure in most pharmaceutical organisations. As noted by Shanmugam *et al.*, (2023) , legacy IT systems, data silos, and outdated quality management platforms are an obstacle to a smooth implementation of BDA tools in QRM workplaces. Most companies are even using paper-based or bi-digital systems, and as a consequence, real-time analytics and cross-platform connectivity are challenging. The issue has also been worsened by the lack of competent data professionals in the quality field in the pharmaceutical industry. Mazzuto and Ciarapica (2019) find that machine learning models and advanced analytics, developed or interpreted by quality teams, frequently lack this technical capacity, thus making it problematic to exploit BDA.

The other important challenge is data governance and regulatory compliance. Strict requirements of use of data, traceability and system validation are imposed with the General Data Protection Regulation (GDPR) and Good Automated Manufacturing Practice (GAMP 5) guidelines. According to Thanasas *et al.*, (2025), it creates a level of complexity in managing data integrity, transparency of the algorithms, and readiness for regulatory audits when using real-time analytics and machine learning. The predictive results of BDA systems will not be valid unless they are properly characterised and validated, or they will not be acceptable to regulatory agencies like the EMA or FDA and will not be useful in QRM.

In spite of these obstacles, chances are enormous. The great opportunity is in predictive and preventive risk management. With the help of the BDA tools, quality failures can be identified at an early stage, ensuring that there is a lower possibility of experiencing deviations, recalls, and regulatory actions(Choi *et al.*, 2017). Furthermore, BDA enables the simplification of resources through which quality teams may direct their attention to high-risk regions instead of wasting their time checking every aspect of low-risk actions manually (Shanmugam *et al.*, 2023).

In Ireland, the country's strategies also promote digital transformation through strategies like the Ireland Industry 4.0 Strategy 2020-2025 that promote digital transformation in most manufacturing sectors such as pharmaceuticals. (Clancy and O'Rourke, 2021) argues that this provides a suitable environment for the adoption of advanced technologies and barriers to adoption are expected to be addressed through the financial incentives and skill development programmes.

2.3 Theories and Models

2.3.1 Technology Acceptance Model

The Technology Acceptance Model (TAM), created by Davis (1989), is a popular theory in the information systems field that explains the user acceptance process and adoption of new technologies. TAM also assumes that there are two key constructs, namely: Perceived Usefulness (PU) and Perceived Ease of Use (PEOU), which determine how the person will use a given technology as an intention and how will they use technology (Holden and Karsh, 2010). PU is the extent to which an individual feels that the usage of a system will benefit the performance of their job, and PEOU is the perception of the user regarding how efficient the system is.

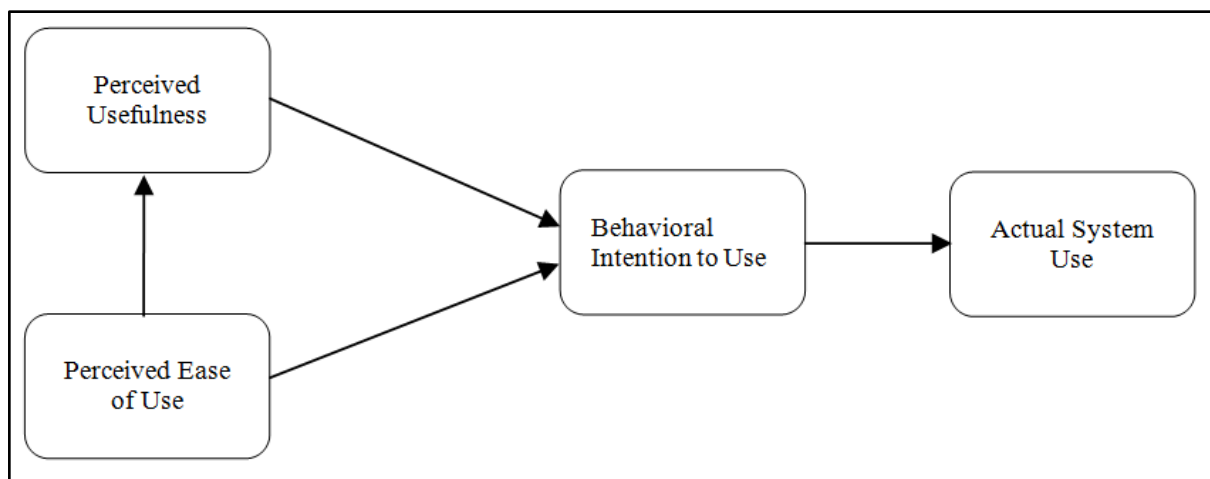


Figure 1: Technology Acceptance Model

(Source: Naeini, 2022)

The given model can be considered especially appropriate when applied to the present-day research that explores the introduction of Big Data Analytics (BDA) into Quality Risk Management (QRM) in the Irish life sciences industry. The BDA utilizes advanced electronic tools, such as machine learning models, data lakes, and visual analytics, and this is why the transition to embracing it cannot occur without the support of people who utilize quality

assurance, risk management, and compliance functions (Al Ateeq *et al.*, 2022). To determine how the perceived benefits and usability affect the readiness to use the new technologies in the QRM structures, such as ICH Q9, the TAM offers a beneficial perspective, especially in a regulated sector such as pharmaceuticals, the industry in which conventional procedures prevail. To give some illustrations, several studies have applied TAM to pharmaceutical and healthcare contexts to examine technology acceptance in the conditions of regulation and operational limitation. In particular, Venkatesh and Bala (2008) have included such external variables as organisational support and system compatibility, which are especially relevant in the pharmaceutical industry. They provide the results showing that the acceptance of data-intensive systems is significantly connected with trust in the system outputs and its perceived compliance with regulation.

In addition, Holden and Karsh (2010) used TAM to measure health informatics adoption and found that although efficacy plays an important role in the intent to adopt an informatics technology, ease of use is sometimes an obstacle in the complex environment where employees do not have high data literacy levels. This aligns with the difficulties of the Irish pharmaceutical industry, with lots of professionals in the field possessing considerable experience in quality systems and perhaps offering comparatively minimal expertise in the utilisation of BDA tools. Nevertheless, TAM critics state that TAM does not explicitly consider the contextual risks like risk culture, compliance requirements, or data governance, which is a vital consideration in QRM environments. Legris *et al.*, (2003) have suggested that simple model constrain its explanatory value in a complex organisational environment where perception of utility and usability do not drive decisions only.

2.3.2 Risk Management Framework

Risk Management Frameworks like the ISO 31000 or ICH Q9 provide organised approaches toward identification, analysis, management and observation of risks of organisations (Suprin *et al.*, 2019). A general risk management framework that can be applied to any industry is ISO 31000, developed by the International Organisation of Standardisation. It focuses on such core values as the identification, the analysis, the evaluation, the treatment and the constant improvement of risks (Kilian *et al.*, 2025). ICH Q9, on the other hand, has been specifically developed to suit the pharmaceutical and life sciences industry, and its particular application is QRM with references to drug development and production. ICH Q9 is a mixture of scientific considerations with risk-based considerations to achieve the quality of the products and safety of the patient (ICH, 2023).

In this study, these types of frameworks are considered as theoretical links, as someone can see that they directly relate to the integration of BDA to QRM. Strong risk schemes, contrary to the use of non-structured methods, are vital in highly regulated industries like those in the pharmaceutical sector (Zhao *et al.*, 2016). Regulatory expectations ICH Q9 are integrated into regulatory expectations by regulatory bodies such as the European Medicines Agency (EMA) and the U.S. FDA. Consequently, any form of innovations, including BDA, should work in line with its principles to be compliant. The more enterprise-centred view of risk recommended by ISO 31000 compares favourably to the more operational view described by ICH Q9, when applied to organisation-wide digital transformation programmes within Irish life sciences organisations.

These frameworks have been confirmed in several studies to be important in the implementation of proactive and data-based risk management. Mulholland (2024) suggests that ICH Q9 supports risk-based decision-making, which perfectly matches with predictive functionality proposed by BDA tools. Their study shows that the combination of ICH Q9 and real-time analytics enhances aviation management and audit readiness. Hutchins (2018) also emphasises the importance of ISO 31000 in improving governing infrastructures and aligning risk consciousness within different departments of any organisation, especially when new technological solutions, such as machine learning, are introduced to the quality system.

Nevertheless, it has its restrictions. The conventional applications of ICH Q9 can be based on qualitative measurements and the manual risk-ranking methods and tools (such as FMEA); these methods cannot only be subjective but also lack consistency (Stocker *et al.*, 2017). A trend disclosed by these explanations of implementing data science as a part of QRM, which in turn expands on the current framework in terms of incorporating data science capabilities: i.e., quantitative analysis in real-time. ISO 31000 has also been criticised further as being too general and therefore not operationally deep to be applicable at a specific industry level unless customised (Leitch, 2010).

2.3.3 Data-Driven Decision-Making Theory

The theory of Data-Driven Decision-Making (DDDM) describes a formal process of strategic or operational decision-making, using data analysis and interpretation and not relying on guess, intuition, or previous experience. It focuses on the application of sure, right on time and applicable information to make judgment, minimise uncertainty and enhance results (Mandinach *et al.*, 2006). DDDM matters in the life sciences sector, especially because

the processes in the pharmaceutical industry are very complex, and there is regulatory oversight, and the cost of quality risk management (QRM) error is so high.

DDDM theory connects to the specific focus of the current research due to its correlation with Big Data Analytics (BDA) applications in the QRM. Since life sciences organisations generate huge volumes of process, product and patient data, it is necessary to make use of this data to make quality decisions. Predictive and prescriptive analytics are supported in DDDM, so that companies become capable of identifying the deviations upstream, tracking them, and proceeding with control actions, to comply with the principles of frameworks, e.g., ICH Q9 and ISO 31000 (Fakhfakh and Mezghani, 2025).

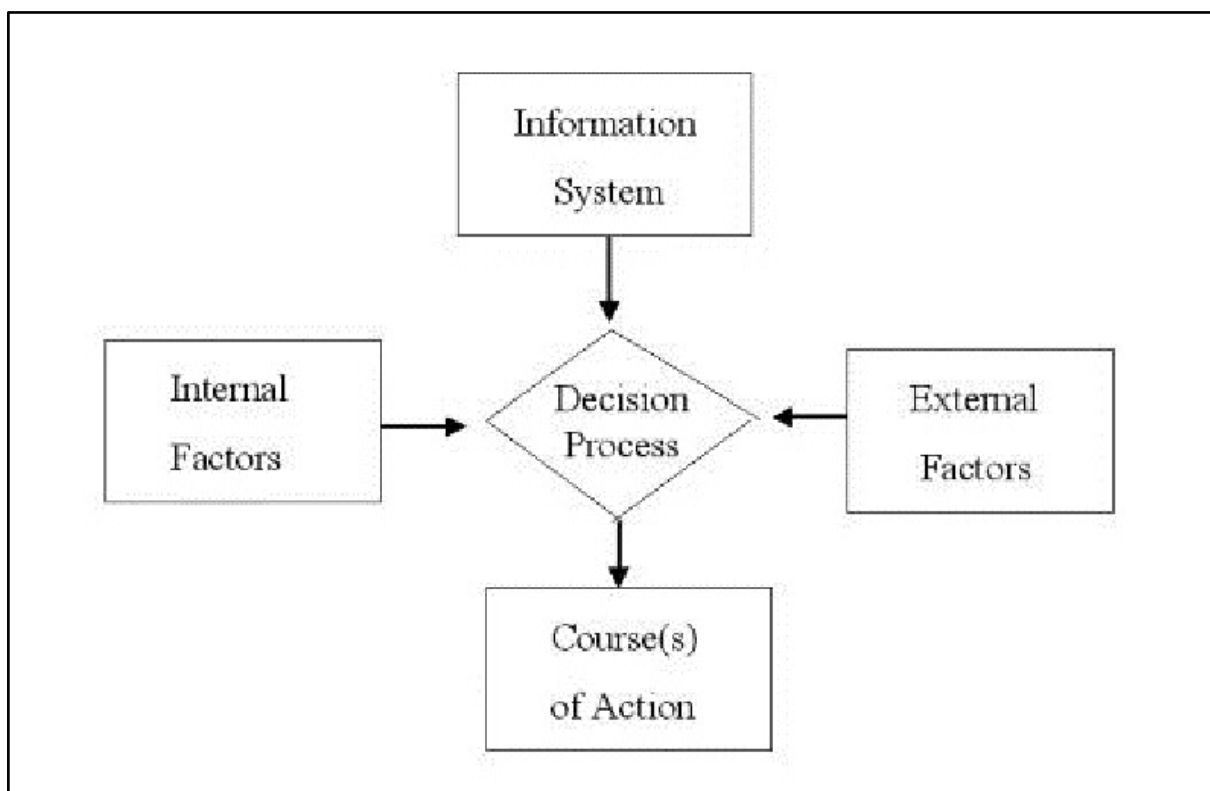


Figure 2: Data-driven decision-making theory

(Source: Picciano, 2012)

There is a powerful stance allowed by scholars to utilise DDDM in life sciences. As an example, Brynjolfsson and McElheran (2016) showed that companies using a data-based approach were 56% more productive than other enterprises. To alleviate the most, they gave examples of scientists who managed to increase productivity by more than 6% after using data-driven techniques in pharmaceutical manufacturing. Similarly, Mikalef *et al.*, (2020) focused on the positive role of data-driven cultures in advancing the level of risk management maturity,

especially with the involvement of organisational commitment to analytics capability and governance.

Additionally, DDDM helps in improving regulatory compliance. Waller and Fawcett (2013) also assume that in the data-driven systems, auditability and traceability of quality-related decision-making are possible, which is essential to pass GMP (Good Manufacturing Practice) and regulatory inspection requirements. The combination of DDDM and visual analytics tools and machine learning also enables companies to attain predictive QRM, as shown in research by Akter and Wamba (2016) , who also associated DDDM with a better ability to make decisions and being quick enough to solve problems in a complex environment.

Nonetheless, there are still obstacles to overcome. Critics such as Sharma *et al.*, (2014) warns that too much data can be like paralysis, as having the wrongly integrated amounts of data can be an issue either in findings or inaction. More so, DDDM relies strongly on the quality of data, infrastructure, and literacy of decision-makers in the interpretation of analytics output (Chen *et al.*, 2012) . A misinterpretation of the data in the field of life sciences, where the quality decision may have major patient consequences, may result in regulatory outcomes or product recall.

2.3.4 Social-Technical System Theory

The theory behind Socio-Technical-Systems (STS) postulates that the effectiveness of any technological intervention or technology implementation in an organisation is correlated to optimal integration of social (people, roles, culture) and technical (tools, processes, infrastructure) subsystems in the organisation (Mumford, 2006) . STS focuses on collective optimising, which implies that neither the social nor technically based systems should prevail, but they should be combined in order to develop sustainable, flexible and efficient organisational systems.

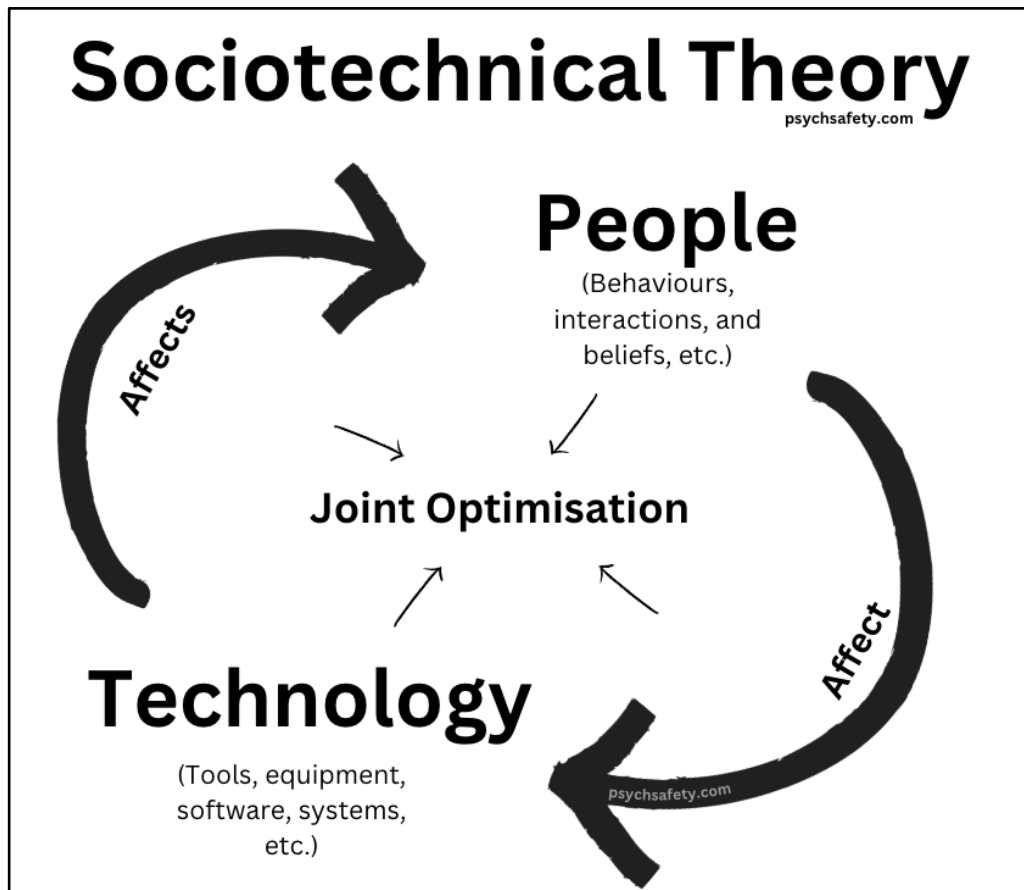


Figure 3: Social-Technical System Theory

(Source: Geraghty, 2024)

The theory is particularly relevant in the subject of the research under the topic of examining the role of BDA in QRM in the Irish life sciences sector. Using BDA solutions such as machine learning models or data lakes does not necessarily lead to an enhanced QRM unless organisational structure, culture of the workforce and decision-making processes are aligned to such solutions (Bednar and Welch, 2020) . In that case, the STS theory is in favour of a comprehensive analysis that takes into account technical possibilities and human elements, including skills, training, acceptance, and ethics issues.

There is a large amount of literature that confirms the applicability of STS as far as health and life sciences are concerned. According to Clegg (2000) , there exists the significance of redesigning the work processes alongside the adoption of the technological aspect so that efficiency and satisfaction of the users can be achieved. Also, Baxter and Sommerville (2011) claim that systems such as QRM in the area of pharmaceutical quality systems require socio-technical integration because decisions are usually made concerning the results of complex

data output interpretation by cross-functional teams. Their warning is that a system so automated that it threatens to undermine human supervision will cause the risk to be blinded. In addition, the seeming similarities between STS theory and resilient system design, the latter of which is quite necessary in regulated industries such as life sciences. The STS frameworks are described by Dzazali *et al.*, (2009) as enabling adaptive, learning focused settings with feedback loops to bring about the continuous enhancement of technology use and quality practices. This comes in handy, especially when trying to comply with the risk-based approach expressed in ICH Q9 that facilitates continual improvement via integration of knowledge and feedback processes.

Nonetheless, as critics have pointed out Ngowi and Mvungi (2018) the details of implementing STS can be elaborate and would need a lot of cooperation and stakeholder support that can be costly. Benefits realisation may be retarded by resistance to change and the lack of cohesion between goals in the technical teams and in the quality assurance staff.

2.4 Conceptual Framework

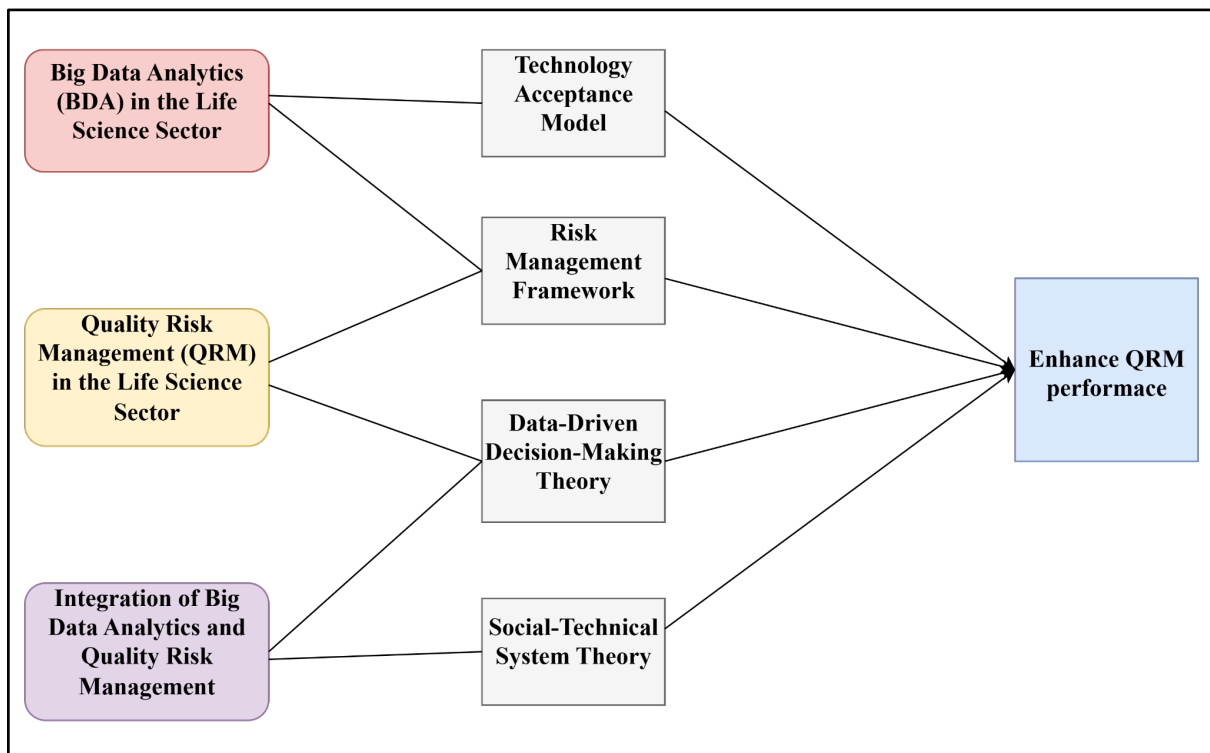


Figure 4: Conceptual framework

(Source: Self-made)

The core themes included in the conceptual framework of the current study are BDA, QRM, and organisational challenges/ opportunities, and they have been subjected to integration with four theoretical frameworks to explain and transform the practice of risk management in the life sciences industry in Ireland. This framework helps the achievement of the study, which seeks to investigate how the BDA tool (machine learning, data lakes, and visual analytics) could be used in QRM frameworks (such as ICH Q9) in order to identify deviation, the improvement of control mechanisms and the data-driven decisions.

TAM elucidates the acceptance of BDA tools by users and measures the ease of use and usefulness of such tools as estimated by QRM professionals. ICH Q9 Risk Management Framework offers a regulatory perspective within which an organised approach to risk identification, evaluation and mitigation can be examined. Data-Driven Decision-Making Theory backs the conversion of raw data into strategic information to achieve QRM improvements. Finally, STS Theory is the theory that separates the connection between people and up-to-date analytics devices, underlining the necessity to balance between technology and human capacity and company culture.

The theories are associated with empirical themes. As an example, the use of BDA tools (Theme 1) directly affects the risk identification and treatment process (Theme 2), and implementation barriers (Theme 3) can affect the performance of analytics. Every theme focuses on the consequence of enhanced QRM performance (Theme 4), which is expressed in predictive control, regulatory compliance, and evidence-based decision-making.

The reasoning presented in this framework offers an outline of the flow of the empirical study, which manages the research design, methods of data collection, and analysis processes based on the strategic goals of the research.

2.5 Literature Gap

It has been observed that BDA can be significantly useful in terms of QRM in life sciences due to the ability to make predictive data-driven decisions. The implementation of regulatory systems such as ICH Q9 in the Irish context does not oppose adherence to technologies and techniques such as machine learning, data lake, and visual analytics. Various theoretical frameworks, such as TAM, Risk Management Framework, Data-Driven Decision-Making Theory, and Socio-Technical Systems Theory, offer an opportunity to mix technology and company practice. The challenges, such as data governance, skills shortage and legacy systems,

exist despite the opportunities. In this review, it lays the foundation of how empirical insights can be evaluated in future research work.

2.6 Chapter Summary

This chapter has given an in-depth literature review about BDA and the QRM of the Irish life sciences industry. It discussed major themes, theoretical foundations and their connection using a conceptual approach. The critical review of the literature on the current research discussed the available research and the lack of it that warrants the conduct of this study. Chapter three will comprise the research methodology, research philosophy, research design and data collection methods and data analysis methods that will influence the empirical study.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This study aims at assessing how BDA can increase the QRM in life sciences industries in Ireland. Research objectives have been described in previous chapters, which entailed a literature review and gave an insight into historical knowledge of the issues, possibilities, and technological trends in incorporating BDA in QRM. This chapter comprises the methodological framework that will be applied to the research.

This research has been conducted based on the Research Onion model developed by Saunders, which offers a step-by-step approach to research design. The model consists of seven layers namely research philosophy, research approach, research strategy, research choices, time horizons and research techniques and procedures. This model provides an in-depth overview of identifying the most suitable methods to attain the research goals.(Saunders and Tosey, 2012)

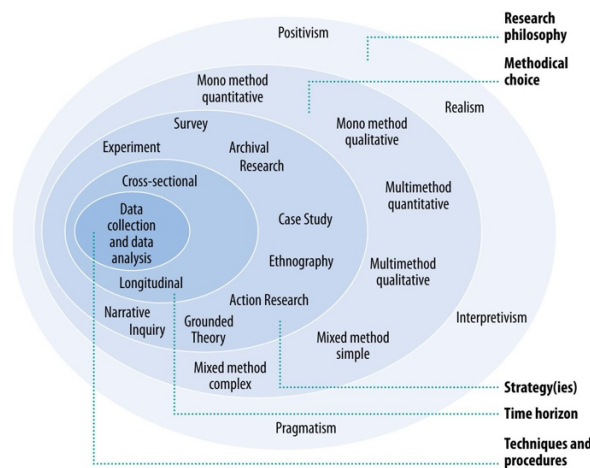


Figure 5: Research onion model

Source : (Saunders and Tosey, 2012)

3.2 Research Philosophy

The nature of the study is positivism and based on the fact that the reality is objective, measurable, and identifiable by way of empirical observation. Positivism can be applied where, one wishes to gather measurable evidence that may indicate a pattern, association, or trend and the study may require a fixed approach like a survey. This aligns with the research aim because the adoption of QRM and BDA could be measured in quantitative terms like the availability of digital tools, the frequency of deviation reduction or audit preparation (Creswell and Creswell, 2017).

The positivist philosophy helps to explore trends and connection between the implementation of BDA and the enhancement of QRM practices. It promotes the use of structured and

standardised tools to collect the objective evidence, including close ended questions in a survey.

This study relies on the positivist approach to identify correlation between the variables as we want to establish explicit correlation between the BDA adoption and QRM adaptation outcomes.

3.3 Research Approach

A research approach is the general plan and rationale that links the research philosophy and the methods selected to collect and analyse data. The two most dominant approaches are deductive and inductive.

Deductive approach starts with existing theories or concepts which are used to form hypothesis or research questions which are later tested based on the data collected. On the other hand, Inductive approach begins with the collection of data and concepts or theories are developed based on the observed patterns (Kumar and Ujire, 2024) . In this study, a deductive research approach is used that aligns with the positivist philosophy. Deductive approach starts with theory and concepts that are already present. Here hypothesis is formulated and then this is put to test by comparing this with empirical evidence. The deductive approach was considered to be suitable as robust conceptual frameworks exist in the literature on QRM and BDA, but in Ireland, there is a gap in existing evidence. Using this method, the paper conducts an experiment to determine whether international results including the use of BDA to enhance audit preparedness, decrease deviations and quicken release of batches apply in the life sciences sector of Ireland.

The inductive approach was discussed and rejected. Building theory on data through induction is more applicable in exploratory research where a minimal amount of theory is involved. In the present study, there is adequate theoretical or empirical text in literature worldwide, and this study is not aimed at producing new theory but to identify the effectiveness of a globally established theory in an Irish context.

3.4 Research methods

Research methods could be defined as techniques and methodologies that seek to gather information required to address the research questions. Research methods are generally categorized into two groups, namely quantitative and qualitative.

Quantitative method addresses numerical, statistical and objective measurement. Surveys, experiments and structured observations are typical examples. Qualitative method refers to non-numerical data including interviews, focus groups or document analysis and focuses on interpretation, meaning and depth (Dehalwar and Sharma, 2024). The quantitative survey is used in this dissertation. The online survey created in google forms was chosen as it seems to be an efficient instrument to collect the data of a relatively large number of professionals in the Irish life sciences sector.

3.5 Research Strategy

A research strategy is the broad plan that converts the research approach and philosophy into effective data collection and analysis (Sahay, 2016). In the research, quantitative survey strategy is chosen, namely online-based survey of professionals within the scope of the Irish life sciences organisations such as pharmaceuticals, biotechnology, medical devices and other related fields.

Surveys are oriented on positivistic philosophy and deductive approach as they allow gathering objective and measurable information about large group of people. The outlined research objectives demand to determine how BDA is being utilized in QRM at present, what results have been obtained, and what are the obstacles. These will be most effectively recorded via structured, standardised questions, which allow comparison between respondents.

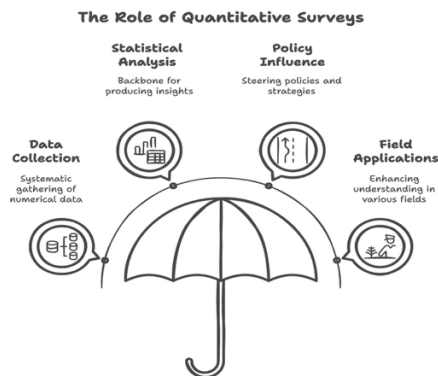


Figure 6: Role of quantitative surveys

Source : (Mhlongo, 2025)

3.6 Time Horizon

The time horizon is the period in which data are gathered and discussed. A cross-sectional study refers to the study that measures data at one specific time, providing a snapshot of a phenomenon. This is mostly applied in research where time and resources are limited. A

longitudinal study is one which gathers data over time and helps researchers to observe changes and trends(Bell *et al.*, 2022).

Cross- sectional study is used in this dissertation. The survey link will be shared to the professionals and responses are gathered within a time period. This study design is aligned to the objectives of the study that is to identify the level of BDA adoption in QRM within the Irish life sciences sector and not to monitor changes over time. Although this method cannot determine causal relationships nor track changes over time, it is suitable given the exploratory nature of the research since the intention is to give a snapshot of what is going on in the industry. Considering the resource and time limitations of this dissertation, cross-sectional design will provide me with an efficient and valid method of collecting representative views to answer the research questions.

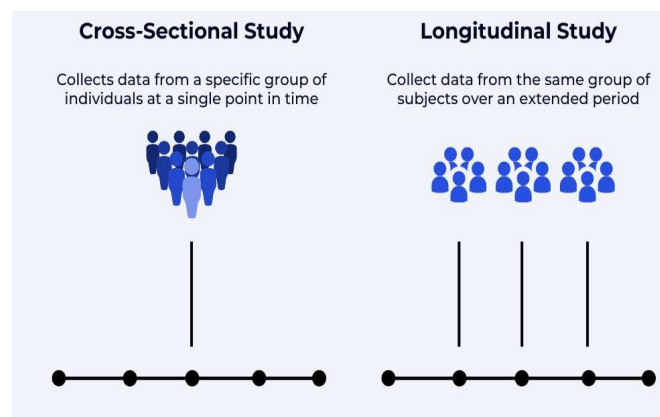


Figure 7: Time horizons

Source : (Appinio, 2023)

3.7 Research subject

The research subject centres on the use of BDA in QRM in the Irish life sciences industry, where the respondents of the study will include the professionals in this industry. These professionals may have expertise in QRM practices and how data-driven tools enable them. The professionals include those working in the quality assurance, regulatory compliance, data analytics, and production operations and digital transformation. Their experiences are vital in evaluating not only the current state of BDA adoption but also the organisational, technological, and regulatory issues faced. Focusing on professionals as the main research

participants, the study guarantees the future findings will be based on the practical experience and represent the real industry practice.

Purposive sampling method was adopted to specifically focus on professionals as they have a better chance of providing informed opinions about the merge of QRM and BDA. Snowball sampling was also used using social networks such as LinkedIn and professional networks to extend reach (Kapur, 2018).

3.8 Data Collection and analysis

Data collection forms an important aspect of the research design, which guarantees that the data which has been collected is in line with the research objectives and philosophy. This dissertation is based on a positivist philosophy and deduction approach, which means that the emphasis is on gathering quantitative, structured data that can be used to objectively assess the amount and influence of BDA on QRM in the Irish life sciences industry. The structured online survey based on Google Forms is used to gather primary data. This platform was chosen because it is easy to access and capable of targeting a diverse professional group. The survey was designed using closed-ended questions, Likert scales and multiple-choice ones to achieve the standardised measurable answers.

The analysis of data was structured in the way that allowed the raw survey data to be transformed into structured, transparent and focused conclusions, directly responding to the research questions. The analysis of findings in this dissertation is set up in a way that will give clear, reliable and objective information with respect to the integration of Big Data analytics BDA in QRM in the Irish life sciences sector. The data will be analysed both with the help of a descriptive and statistical methods according to the positivist philosophy and deductive approach that is being used in this study.

The statistical methods will include both descriptive and inferential statistics, with a correlation to examine statistical relationship between variables, regression to identify identified predictors of the outcome, and chi-square testing to assess statistical relationship between categorical variables.”

Sample size

Validity and credibility of findings in survey-based research relies on providing an appropriate sample size. The sample size was calculated using the sample size calculator on SurveyMonkey

where 126 was the recommended sample size. The number of valid responses was 109 and was approaching the target and was adequate to analyse on an overall basis but with possible limitations upon subgroup analysis. Respondents represented a variety of roles including quality, production operations, digital transformation and data analytics. 109 responses were received out of which 103 were used after data cleaning. Although this is slightly lower than the target, the sampled is close enough to make overall results valid and compliant with the minimum threshold of statistical validity in research based on a survey. With the high population base of the Irish life sciences sector, 100-plus responses allow sufficient precision in drawing substantive conclusions, although subgroup comparisons may lack the statistical power of the total response.

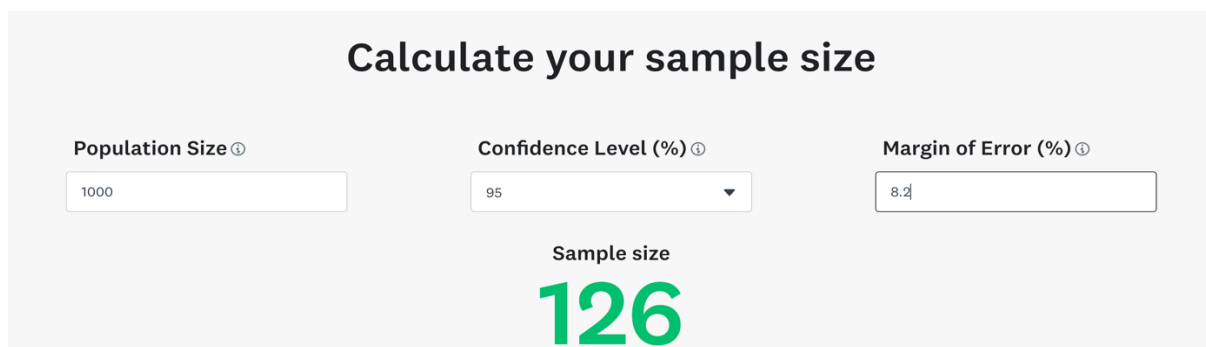


Figure 8: Sample size calculation

Source: Self made

CHAPTER 4: ANALYSIS AND FINDINGS

4.1 Introduction

This chapter will show the complete results of the research on Irish life sciences practitioners on the implementation of BDA in QRM. Five research questions will be answered as part of the analysis to determine the current level of implementation, gain realization, obstacles to adoption, association of organizational capabilities together with strategic measures of transformation to improve BDA integration. The results will be organized to incorporate both descriptive and inferential statistics as presented in terms of a correlation and regression modeling.

The chapter will start with descriptive statistics that will give the present position of the industry on the BDA adoption and organizational preparedness. Thereafter, the statistical analysis of each of these research questions will be developed by using cross-tabulation, correlation analysis and regression modeling to identify any dominant relationships that exist between highly important variables. The analysis will show the level of BDA adoption in the organizations, the gaps between the awareness and advanced usage, and give a perspective to the strategy of transformations to effectively integrate BDA in quality risk management activities.

4.2 Analysis

Descriptive statistics of all variables

	Descriptive Statistics									
	N Statistic	Minimum Statistic	Maximum Statistic	Mean Statistic	Std. Deviation Statistic	Variance Statistic	Skewness		Kurtosis	
							Statistic	Std. Error	Statistic	Std. Error
1.What is your current area of expertise?	103	1	5	2.12	1.123	1.261	.656	.238	-.629	.472
2.What type of company do you work in?	103	1	4	1.97	.902	.813	.713	.238	-.184	.472
3.How will you rate your Company's Digital maturity?	103	1	5	2.73	1.173	1.376	.325	.238	-.596	.472
4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	103	1	3	1.65	.882	.779	.752	.238	-1.298	.472
5.If Yes, which BDA tools are applied in QRM?	87	1	4	1.94	.854	.729	.226	.258	-1.314	.511
6.What do you consider as the main obstacles to the implementation of BDA in your QRM processes?	103	1	5	2.92	1.226	1.504	.313	.238	-.946	.472
7.How confident are you that your company will handle data governance for QRM?	103	1	4	2.15	.879	.773	.327	.238	-.618	.472
8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	103	1	3	2.16	.538	.289	.119	.238	.202	.472
9.Which will be the most strategic improvements needed to your QRM approach in your organisation?	103	1	6	2.78	1.527	2.332	.538	.238	-.806	.472
10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?	103	1	5	1.86	1.121	1.256	1.169	.238	.557	.472
11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	103	1	3	2.04	.713	.508	-.056	.238	-1.004	.472
12.What are the benefits your company has achieved with use of BDA in QRM?	103	1	6	2.70	1.644	2.703	.551	.238	-1.011	.472
Valid N (listwise)	87									

Figure 9:Descriptive statistics of all variables

(Source: SPSS)

The descriptive statistics investigation of 103 Irish life sciences practitioners demonstrates that the industry is ready to reinvent in terms of Big Data Analytics (BDA) involvement in Quality Risk Management (QRM).

Current State

The results reflected in the respondents show that the experience in BDA is relatively low (mean 2.12 years) and that there is a large disparity in digital maturity between the

organizations (mean 2.73, SD 1.173). The awareness of BDA tools in QRM is moderate (mean = 1.94), whereas implementation is at a low level (mean = 1.65), which points to a significant gap in the implementation of the BDA tools in QRM.

Implementation Barriers

There is strong variability in reported obstacles (mean = 2.92, SD = 1.226), indicating a broad variation of organizational challenges of technical, strategic, and resource issues. Moderate scores of data governance (mean = 2.15) and workforce readiness (mean = 2.16) suggest that the organization needs to develop capabilities.

Future Outlook

In spite of these concerns related to implementation, organizations have a high expectation at the strategic improvements QRM approaches can bring (mean = 2.78) with most organizations realizing the relevance of BDA in the future of the sector (mean = 1.86). But the low system integration levels (mean = 2.04) indicate acute deficiency in terms of critical infrastructure.

The figures show a transitional industry in which BDA opportunities are being acknowledged but not yet being implemented. To ensure success, it is necessary to deal with various organizational obstacles, strengthen workforce capacity and better integrate systems to close the gap between awareness and application (Mukhuty *et al.*, 2022)

RQ1: Implementation Status of Big Data Analytics in Quality Risk Management

Statistics		
4.Does your company apply Big		
N	Valid	103
	Missing	0
Mean		1.65
Median		1.00
Mode		1
Std. Deviation		.882
Minimum		1
Maximum		3

4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	64	62.1	62.1	62.1
	No	11	10.7	10.7	72.8
	Not sure	28	27.2	27.2	100.0
Total		103	100.0	100.0	

The statistical data in these figures further provide important information about how Big Data Analytics (BDA) has been used in Quality Risk Management (QRM) practices in Irish life sciences firms, addressing the research question of the magnitude of the adoption of BDA directly.

The descriptive statistics show that the level of BDA implementation is moderate with the mean score of 1.65 and median of 1.00 based on what seems to be a three-point scale. This indicates that although some firms have started embedding BDA in their QRM operations, the use is still not prevalent. The standard deviation of 0.882 shows that there is significant discrepancy in the implementation levels among the surveyed organization and that BDA adoption in Ireland is highly disparate in the Irish life sciences sector.

The frequency distribution will give more details on the present position of implementation. Importantly, it would be worth noting that the percentage of the 103 companies that have made use of BDA to an extent in their QRM practices is 62.1%, which is quite large. Nevertheless, this number should be viewed in combination with the fact that 27.2% of participants responded with uncertainty (“Not sure”), signifying a possible lack of awareness or knowledge of the BDA uses in QRM settings in organisations.

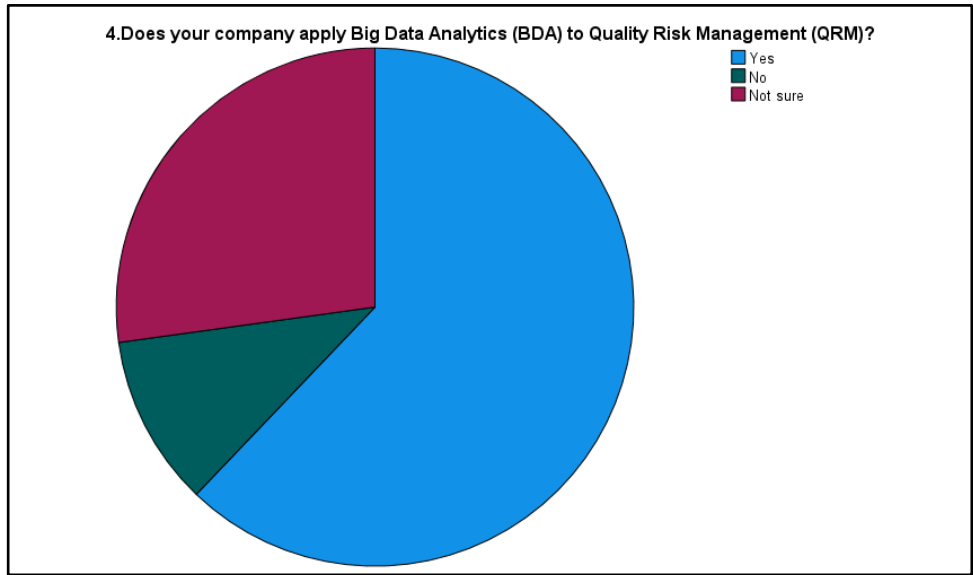


Figure 10: Frequency analysis

(Source: SPSS)

The fact that 10.7% of companies directly state that their companies do not utilize BDA in QRM, along with the corporate percentage who remain undecided, reveals that Irish companies have not fully integrated or appreciated BDA in QRM. This gives tremendous scope to develop and grow in this field.

The results are in line with the overall digital transformation difficulties in traditional industries as the life sciences industry has more regulatory complexity and risk-averse cultures which may result in a slower adoption rate (Dilshan Kangara, 2025). There is still much potential to increase and strategically develop QRM through BDA implementation within Irish life sciences companies as the data suggests they are still in the early-to-moderate stages of the BDA process under the QRM.

Case Processing Summary						
	Valid		Cases Missing		Total	
	N	Percent	N	Percent	N	Percent
4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)? * 2. What type of company do you work in?	103	100.0%	0	0.0%	103	100.0%

4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)? * 2.What type of company do you work in? Crosstabulation

		2.What type of company do you work in?					
			Pharmaceutic al	Medical Device	Biotechnology	Others	Total
4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	Yes	Count	21	29	7	7	64
		% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	32.8%	45.3%	10.9%	10.9%	100.0%
		% within 2.What type of company do you work in?	60.0%	65.9%	43.8%	87.5%	62.1%
	No	Count	4	4	2	1	11
		% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	36.4%	36.4%	18.2%	9.1%	100.0%
		% within 2.What type of company do you work in?	11.4%	9.1%	12.5%	12.5%	10.7%
	Not sure	Count	10	11	7	0	28
		% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	35.7%	39.3%	25.0%	0.0%	100.0%
		% within 2.What type of company do you work in?	28.6%	25.0%	43.8%	0.0%	27.2%
Total	Count	35	44	16	8	103	
	% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	34.0%	42.7%	15.5%	7.8%	100.0%	
	% within 2.What type of company do you work in?	100.0%	100.0%	100.0%	100.0%	100.0%	

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	5.914 ^a	6	.433
Likelihood Ratio	7.843	6	.250
Linear-by-Linear Association	.254	1	.614
N of Valid Cases	103		

a. 7 cells (58.3%) have expected count less than 5. The minimum expected count is .85.

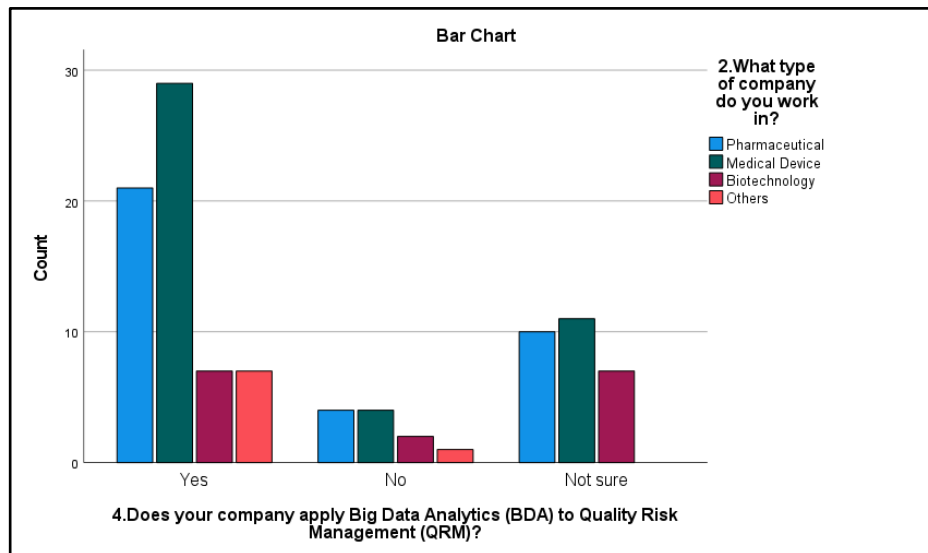


Figure 11: Cross tabulation analysis

(Source: SPSS)

As shown by the survey, there exists evidence that the adoption of Big Data Analytics (BDA) into the Quality risk Management (QRM) practices of Irish life sciences companies is serious and has reached meaningful levels, but there is still much room to grow.

The cross-tabulation illustration shows that 62.1% of the companies (64 out of 103) have adopted BDA in their QRM, which has been a highly positive outlook in the use of advanced analytics in quality management. Such adoption levels imply that most Irish life sciences organizations have understood the strategic importance of data-driven risk assessment and risk-mitigation(Qhal, 2025). The pharmaceutical industry is a leader in transformation with 21 companies under bacterial BDA QRM applications and comparable to other industries of use in medical devices with 29 implementations, which is indicative of a drive by firms in this sector to use technology to achieve better quality.

It is empowering that the area-specific adoption trends are encouraging across segments of the life sciences industry. The pharmaceutical industry exhibits an adoption rate of 60.0% in the industry whereas the medical device industry boasts an amazing adoption rate of 65.9%. Even the smaller biotechnology industry, which is included in the sample, has a healthy 43.8% adoption rate, indicating that BDA integration is prevalent across a wide swath of life sciences applications.

The statistical analysis proves the quality of these results, the correlations between company types and BDA adoption patterns remain stable as the Chi-Square (Chi-square = 5.914, $p = 0.433$) test values. The fact that there were 103 valid responses collected without missing data makes these insights have more credibility.

With 10.7 percent of firms yet to show certainty of the BDA implementation status as well as 27.2% being yet to adopt these technologies, there is a clear potential of growth of firms in the sector. This is a good starting point with the current adoption level of 62.1% that gives Irish life sciences organizations a positive position for further digital transformation in quality risk management. This development proves that the industry is well ready to adopt new models of operation which can maximize the safety of products, compliance with regulatory bodies, and efficiency of operations based on data-driven decisions (Gade, 2021).

		Correlations			
		3.How will you rate your Company's Digital maturity?	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	7.How confident are you that your company will handle data governance for QRM?	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?
3.How will you rate your Company's Digital maturity?	Pearson Correlation	1	-.064	.410**	.001
	Sig. (2-tailed)		.519	<.001	.992
	N	103	103	103	103
4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	Pearson Correlation	-.064	1	.104	.396**
	Sig. (2-tailed)	.519		.295	<.001
	N	103	103	103	103
7.How confident are you that your company will handle data governance for QRM?	Pearson Correlation	.410**	.104	1	.179
	Sig. (2-tailed)	<.001	.295		.071
	N	103	103	103	103
11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	Pearson Correlation	.001	.396**	.179	1
	Sig. (2-tailed)	.992	<.001	.071	
	N	103	103	103	103

** . Correlation is significant at the 0.01 level (2-tailed).

Figure 12: Correlation analysis

(Source: SPSS)

The correlation analysis provides interesting feedback on the application of Big Data Analytics to Quality Risk Management practices among life sciences firms in Ireland (Eich, 2022). The data shows a moderate positive correlation (0.410) between the digital maturity of companies and their confidence about managing data governance in relation to QRM, implying that companies with better digital backbones are in a better place to deploy analytics capabilities. Most preferably is the considerable relationship (0.396) between implementation of Big Data Analytics and integration of QRM systems with other enterprise services like MES Systems,

LIMS Systems, and ERP systems. This implies that companies using Big Data Analytics are developing more cross-connected, comprehensive quality management systems that increase the efficiency of operations and data-informed decision making.

The significant correlation (0.519) between digital maturity score and adoption of Big Data Analytics supports the fact that Irish life sciences companies are specifically establishing fundamental capabilities to enable advanced analytics as a priority. These results indicate that the industry is moving toward more advanced and data-driven QRM strategies, and digital transformation can be viewed as a driver to better quality control practices (Kumar *et al.*, 2023).

RQ2. Benefits and Value Realization of BDA Integration

Case Processing Summary						
	Valid		Cases Missing		Total	
	N	Percent	N	Percent	N	Percent
	12.What are the benefits your company has achieved with use of BDA in QRM? * 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	103	100.0%	0	0.0%	103

12.What are the benefits your company has achieved with use of BDA in QRM? * 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)? Crosstabulation

		4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?			Total	
		Yes	No	Not sure		
12.What are the benefits your company has achieved with use of BDA in QRM?	Data driven decision-making	Count	23	0	12	35
		% within 12.What are the benefits your company has achieved with use of BDA in QRM?	65.7%	0.0%	34.3%	100.0%
		% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	35.9%	0.0%	42.9%	34.0%
	Faster batch release	Count	13	1	6	20
		% within 12.What are the benefits your company has achieved with use of BDA in QRM?	65.0%	5.0%	30.0%	100.0%
		% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	20.3%	9.1%	21.4%	19.4%
	Better audit readiness	Count	7	6	3	16
		% within 12.What are the benefits your company has achieved with use of BDA in QRM?	43.8%	37.5%	18.8%	100.0%
		% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	10.9%	54.5%	10.7%	15.5%
Fewer deviations	Count	10	1	0	11	
	% within 12.What are the benefits your company has achieved with use of BDA in QRM?	90.9%	9.1%	0.0%	100.0%	
	% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	15.6%	9.1%	0.0%	10.7%	
Cost savings in quality management	Count	8	1	6	15	
	% within 12.What are the benefits your company has achieved with use of BDA in QRM?	53.3%	6.7%	40.0%	100.0%	
	% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	12.5%	9.1%	21.4%	14.6%	
No measurable benefits	Count	3	2	1	6	
	% within 12.What are the benefits your company has achieved with use of BDA in QRM?	50.0%	33.3%	16.7%	100.0%	
	% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	4.7%	18.2%	3.6%	5.8%	
Total	Count	64	11	28	103	
	% within 12.What are the benefits your company has achieved with use of BDA in QRM?	62.1%	10.7%	27.2%	100.0%	
	% within 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	100.0%	100.0%	100.0%	100.0%	

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	26.285 ^a	10	.003
Likelihood Ratio	27.721	10	.002
Linear-by-Linear Association	.016	1	.900
N of Valid Cases	103		

a. 11 cells (61.1%) have expected count less than 5. The minimum expected count is .64.

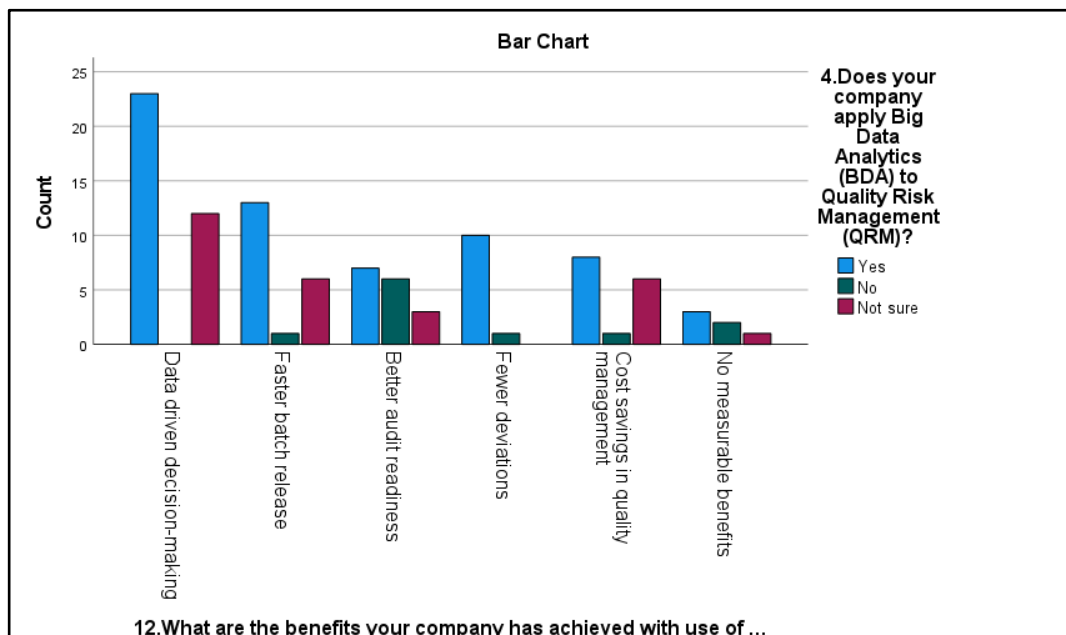


Figure 13: Crosstabulation analysis

(Source: SPSS)

The crosstabulation analysis indicates that there are considerable gains that Irish life sciences companies have acquired by integrating Big Data Analytics (BDA) in Quality Risk Management (QRM). The data shows that BDA uses multiple aspects of beneficial improvements in the operations of a company (Mulholland, 2024).

The predominant advantage of BDA incorporation into an organization concerns data-driven decision-making, as 65.7% of companies that have adopted BDA state that it has empowered them to make better decisions. This means 35.9% of all of the organizations surveyed who have seen BDA produce fundamental changes to the way quality risks are evaluated and dealt with. The change between intuitive and evidence-based responses allows better identification and risk mitigation strategies (Tiwari, 2024).

The capabilities with respect to operational efficiency are also very robust, with 65.0% of BDA users recording improved batch release cycles. This speeding up of the production schedule has a direct effect on market alertness and competitiveness. Also, 90.9% of the companies that have adopted BDA say they are experiencing a reduction in deviations indicating stronger process control and fewer quality-related interruptions.

The optimization of quality management is reflected in the cost savings stated by 53.3% of the BDA-adopting organizations. Associations found in the Chi-square test result ($p=0.003$) support a statistically significant value relating BDA adoption with these benefits and projects the strategic worth of analytics incorporation to achieve quality risk management systems in the Irish life sciences industry.

Descriptive Statistics			
	Mean	Std. Deviation	N
12.What are the benefits your company has achieved with use of BDA in QRM?	2.70	1.644	103
3.How will you rate your Company's Digital maturity?	2.73	1.173	103
7.How confident are you that your company will handle data governance for QRM?	2.15	.879	103
8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	2.16	.538	103
11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	2.04	.713	103

Figure 14:Descriptive analysis

(Source: SPSS)

Analysis shows strong arguments in favour of the tremendous upside of the incorporation of Big Data Analytics (BDA) into Quality Risk Management (QRM) in Irish life sciences institutions(Mulholland, 2024). The descriptive statistics also show that the survey respondents can identify moderate to high dimensions of benefits in all the dimensions measured with a mean score between 2.04 to 2.73 on the measurement scale.

Correlations						
		12.What are the benefits your company has achieved with use of BDA in QRM?	3.How will you rate your Company's Digital maturity?	7.How confident are you that your company will handle data governance for QRM?	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?
Pearson Correlation	12.What are the benefits your company has achieved with use of BDA in QRM?	1.000	.140	.221	-.224	.060
	3.How will you rate your Company's Digital maturity?	.140	1.000	.410	.114	.001
	7.How confident are you that your company will handle data governance for QRM?	.221	.410	1.000	-.235	.179
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	-.224	.114	-.235	1.000	-.476
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.060	.001	.179	-.476	1.000
Sig. (1-tailed)	12.What are the benefits your company has achieved with use of BDA in QRM?	.	.079	.013	.012	.273
	3.How will you rate your Company's Digital maturity?	.079	.	.000	.125	.496
	7.How confident are you that your company will handle data governance for QRM?	.013	.000	.	.008	.036
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	.012	.125	.008	.	.000
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.273	.496	.036	.000	.
N	12.What are the benefits your company has achieved with use of BDA in QRM?	103	103	103	103	103
	3.How will you rate your Company's Digital maturity?	103	103	103	103	103
	7.How confident are you that your company will handle data governance for QRM?	103	103	103	103	103
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	103	103	103	103	103
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	103	103	103	103	103

Figure 15:Correlation analysis

(Source: SPSS)

The correlation analysis yields especially interesting information on the interrelatedness of BDA benefits. A positive relationship is also observed between the ratings of digital maturity

levels and confidence in data governance capabilities (0.410) with stronger ratings of digital maturity correlating strongly with confidence in data governance capabilities. Finally, the fact that the benefit of BDA and the confidence in data governance are moderately correlated (0.221) is also evidence that effective implementation leads to the establishment of organizational trust towards data-driven decision making.

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	Change Statistics			Sig. F Change
						F Change	df1	df2	
1	.308 ^a	.095	.058	1.596	.095	2.562	4	98	.043

a. Predictors: (Constant), 11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?, 3.How will you rate your Company's Digital maturity?, 7.How confident are you that your company will handle data governance for QRM?, 8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?

b. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	26.097	4	6.524	2.562	.043 ^b
	Residual	249.573	98	2.547		
	Total	275.670	102			

a. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

b. Predictors: (Constant), 11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?, 3.How will you rate your Company's Digital maturity?, 7.How confident are you that your company will handle data governance for QRM?, 8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	3.717	1.181		3.147	.002
	3.How will you rate your Company's Digital maturity?	.161	.152	.115	1.057	.293
	7.How confident are you that your company will handle data governance for QRM?	.244	.208	.130	1.175	.243
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	-.746	.348	-.244	-2.142	.035
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	-.183	.253	-.079	-.723	.471

a. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

Residuals Statistics ^a					
	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	1.52	3.96	2.70	.506	103
Residual	-2.257	3.597	.000	1.564	103
Std. Predicted Value	-2.333	2.489	.000	1.000	103
Std. Residual	-1.414	2.254	.000	.980	103

a. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

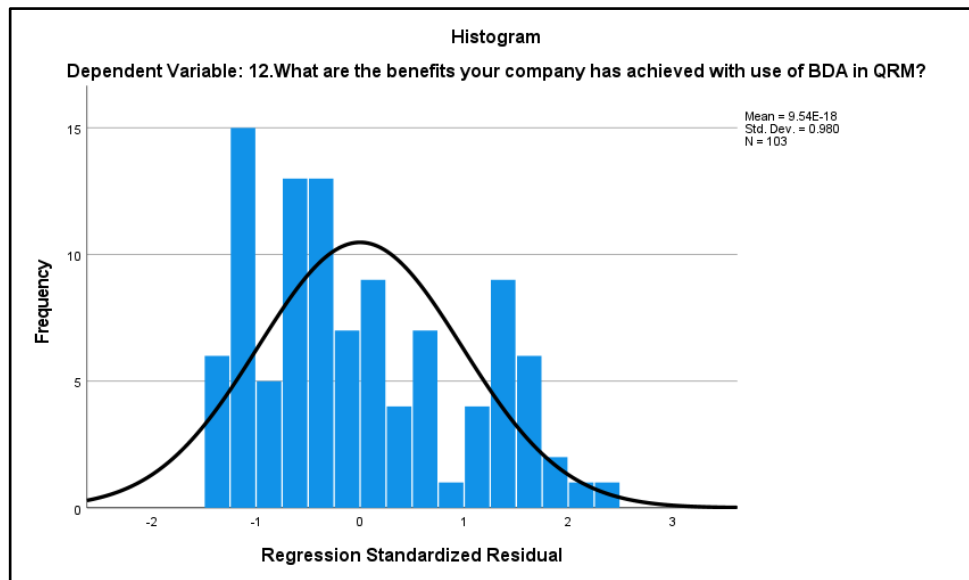


Figure 16:Regression model analysis

(Source: SPSS)

The regression model proves to be statistically significant ($F=2.562$, $p=0.043$), and it explains almost 9.5% of the variance in perceived BDA benefits. The coefficients indicate that the readiness to using data-driven risk management tools impacts the benefit realization significantly. This observation underpins that investing in the education of employees and the change management processes will deliver higher returns on the technology investment even when BDA is implemented ensuring the organization has a higher quality risk management abilities and competitive standing within the pharmaceutical industry (Bertello *et al.*, 2020).

RQ3. Technological, Organizational, and Regulatory Obstacles

Correlations					
		3.How will you rate your Company's Digital maturity?	6.What do you consider as the main obstacles to the implementation of BDA in your QRM processes?	7.How confident are you that your company will handle data governance for QRM?	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?
3.How will you rate your Company's Digital maturity?	Pearson Correlation	1	-.185	.410**	.114
	Sig. (2-tailed)		.061	<.001	.251
	N	103	103	103	103
6.What do you consider as the main obstacles to the implementation of BDA in your QRM processes?	Pearson Correlation	-.185	1	-.180	-.086
	Sig. (2-tailed)	.061		.068	.390
	N	103	103	103	103
7.How confident are you that your company will handle data governance for QRM?	Pearson Correlation	.410**	-.180	1	-.235*
	Sig. (2-tailed)	<.001	.068		.017
	N	103	103	103	103
8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	Pearson Correlation	.114	-.086	-.235*	1
	Sig. (2-tailed)	.251	.390	.017	
	N	103	103	103	103

** . Correlation is significant at the 0.01 level (2-tailed).
 * . Correlation is significant at the 0.05 level (2-tailed).

Figure 17: Correlation analysis

(Source: SPSS)

The correlation analysis conducted provides valuable insights on the technological, organizational and regulatory barriers to Irish life science companies adopting Big Data Analytics (BDA) to manage Quality Risk Management (QRM). The information signals differences in interconnectedness of core implementation variables, and forms the basis of a line of thinking on the obstacles, which must be overcome in an organization (Lipa, 2021)

The positive effect of the digital maturity assessment on confidence in data governance capabilities has a moderate ($r = 0.410$, $p < 0.001$) correlation, which indicates that organizations with more powerful technological backs need fewer resources to overcome implementation issues in their ranks. This association shows that the companies pursuing development of a digital infrastructure also create the confidence in the company to deal with both the organizational complexity and data governance requirements, effectively managing to break down both the technological and organizational barriers (Nagrani *et al.*, 2025).

Interestingly, the low but negative correlation ($r = -0.185$) obtained between digital maturity and the perceived BDA implementation barriers indicate that more technologically advanced organizations face fewer barriers to deployment. This suggests that digital capability investment should be considered an upstream measure against typical implementation issues, especially on integration and data management complexities.

The organizational aspect is also reflected in the relationship demonstrated between confidence in data governance and the appropriateness of equipping the workforce with data-driven tools, which was a moderate negative correlation ($r = -0.235$, $p < 0.05$). This correlation indicates that organizations having well-established data governance mechanisms value the extreme necessity of investing in relevant technological resources, which involves a combination of organizational preparedness and technological infrastructure (Soyege *et al.*, 2024).

Regarding the regulatory aspect, the direct correlations reflect moderate relationships, yet, the clear trend is that more digital mature and capable data governance organizations have greater chances to perform under regulatory pressures. It is validated by the statistical significance of many correlations ($p < 0.01$ and $p < 0.05$), indicating that when the technological infrastructure, organizational abilities in relation to BDA, and regulatory preparedness are considered comprehensively, synergistic effects can be achieved to enable the development of successful implementation of BDA in QRM applications.

RQ4. Digital Maturity, Data Governance, and Employee Competency Relationships

Correlations						
		3.How will you rate your Company's Digital maturity?	7.How confident are you that your company will handle data governance for QRM?	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?
3.How will you rate your Company's Digital maturity?	Pearson Correlation	1	.410**	.114	-.064	.001
	Sig. (2-tailed)		<.001	.251	.519	.992
	N	103	103	103	103	103
7.How confident are you that your company will handle data governance for QRM?	Pearson Correlation	.410**	1	-.235*	.104	.179
	Sig. (2-tailed)	<.001		.017	.295	.071
	N	103	103	103	103	103
8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	Pearson Correlation	.114	-.235*	1	-.194*	-.476**
	Sig. (2-tailed)	.251	.017		.049	<.001
	N	103	103	103	103	103
4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	Pearson Correlation	-.064	.104	-.194*	1	.396**
	Sig. (2-tailed)	.519	.295	.049		<.001
	N	103	103	103	103	103
11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	Pearson Correlation	.001	.179	-.476**	.396**	1
	Sig. (2-tailed)	.992	.071	<.001	<.001	
	N	103	103	103	103	103

** . Correlation is significant at the 0.01 level (2-tailed).
* . Correlation is significant at the 0.05 level (2-tailed).

Figure 18: Correlation analysis

(Source: SPSS)

The correlation analysis allows proving the existence of significant positive relations, which can characterize the strategic priority of the digital maturity, data governance, and employee competency in the effective BDA- aided QRM implementation in Irish life sciences organizations (LOUGHLIN, 2021).

The high positive relationship linking the digital maturity and data governance confidence ($r = 0.410$, $p < 0.01$) reveals that the more the level of digital maturity, the better the organization is prepared to have reliable data governance processes. This observation indicates that digital transformation projects develop the basics of infrastructure required to support data management practices, which is imperative in good risk management systems (Malempati *et al.*, 2023).

In addition, there is a positive relationship between the use of BDA to implement QRM and system integration ($r = 0.396$, $p < 0.01$), indicating that the use of BDA to implement QRM is directly linked to the organizational state of readiness in terms of the digital infrastructure.

Organizations that have made digital maturity investments are in a better position to integrate advanced analytics platforms with their current quality management systems (Akhmatova *et al.*, 2022).

The competency of the workforce has significant correlations with the data governance as well as the systems integration capabilities. This shows that employee skills improvement tracks technological change, providing a synergistic effect on the overall QRM performance. Organisations that take human capital development and digital infrastructure investments seriously stand a better chance of portraying positive quality risk management results aided by BDA and thereafter have stronger competition in the highly regulated Irish life sciences sector (Matthews, 2021)

Descriptive Statistics			
	Mean	Std. Deviation	N
12.What are the benefits your company has achieved with use of BDA in QRM?	2.70	1.644	103
3.How will you rate your Company's Digital maturity?	2.73	1.173	103
7.How confident are you that your company will handle data governance for QRM?	2.15	.879	103
8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	2.16	.538	103
11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	2.04	.713	103
2.What type of company do you work in?	1.97	.902	103
4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	1.65	.882	103

Correlations								
		12.What are the benefits your company has achieved with use of BDA in QRM?	3.How will you rate your Company's Digital maturity?	7.How confident are you that your company will handle data governance for QRM?	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	2.What type of company do you work in?	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?
Pearson Correlation	12.What are the benefits your company has achieved with use of BDA in QRM?	1.000	.140	.221	-.224	.060	-.145	-.012
	3.How will you rate your Company's Digital maturity?	.140	1.000	.410	.114	.001	-.119	-.064
	7.How confident are you that your company will handle data governance for QRM?	.221	.410	1.000	-.235	.179	-.106	.104
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	-.224	.114	-.235	1.000	-.476	.131	-.194
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.060	.001	.179	-.476	1.000	-.059	.396
	2.What type of company do you work in?	-.145	-.119	-.106	.131	-.059	1.000	-.050
	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	-.012	-.064	.104	-.194	.396	-.050	1.000
Sig. (1-tailed)	12.What are the benefits your company has achieved with use of BDA in QRM?	.	.079	.013	.012	.273	.072	.451
	3.How will you rate your Company's Digital maturity?	.079	.	.000	.125	.496	.116	.259
	7.How confident are you that your company will handle data governance for QRM?	.013	.000	.	.008	.036	.143	.147
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	.012	.125	.008	.	.000	.094	.025
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.273	.496	.036	.000	.	.276	.000
	2.What type of company do you work in?	.072	.116	.143	.094	.276	.	.308
	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	.451	.259	.147	.025	.000	.308	.
N	12.What are the benefits your company has achieved with use of BDA in QRM?	103	103	103	103	103	103	103
	3.How will you rate your Company's Digital maturity?	103	103	103	103	103	103	103
	7.How confident are you that your company will handle data governance for QRM?	103	103	103	103	103	103	103
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	103	103	103	103	103	103	103
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	103	103	103	103	103	103	103
	2.What type of company do you work in?	103	103	103	103	103	103	103
	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	103	103	103	103	103	103	103

Model Summary^b

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	Change Statistics			Sig. F Change
						F Change	df1	df2	
1	.324 ^a	.105	.049	1.603	.105	1.874	6	96	.093

a. Predictors: (Constant), 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?, 2.What type of company do you work in?, 3.How will you rate your Company's Digital maturity?, 8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?, 7.How confident are you that your company will handle data governance for QRM?, 11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?

b. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	28.896	6	4.816	1.874	.093 ^b
	Residual	246.774	96	2.571		
	Total	275.670	102			

a. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

b. Predictors: (Constant), 4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?, 2.What type of company do you work in?, 3.How will you rate your Company's Digital maturity?, 8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?, 7.How confident are you that your company will handle data governance for QRM?, 11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	4.066	1.233		3.298	.001
	3.How will you rate your Company's Digital maturity?	.137	.155	.098	.889	.376
	7.How confident are you that your company will handle data governance for QRM?	.247	.209	.132	1.180	.241
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	-.700	.353	-.229	-1.984	.050
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	-.139	.272	-.060	-.510	.611
	2.What type of company do you work in?	-.173	.179	-.095	-.967	.336
	4.Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?	-.084	.197	-.045	-.428	.670

a. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

Residuals Statistics^a

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	1.30	4.12	2.70	.532	103
Residual	-2.250	3.432	.000	1.555	103
Std. Predicted Value	-2.636	2.671	.000	1.000	103
Std. Residual	-1.403	2.141	.000	.970	103

a. Dependent Variable: 12.What are the benefits your company has achieved with use of BDA in QRM?

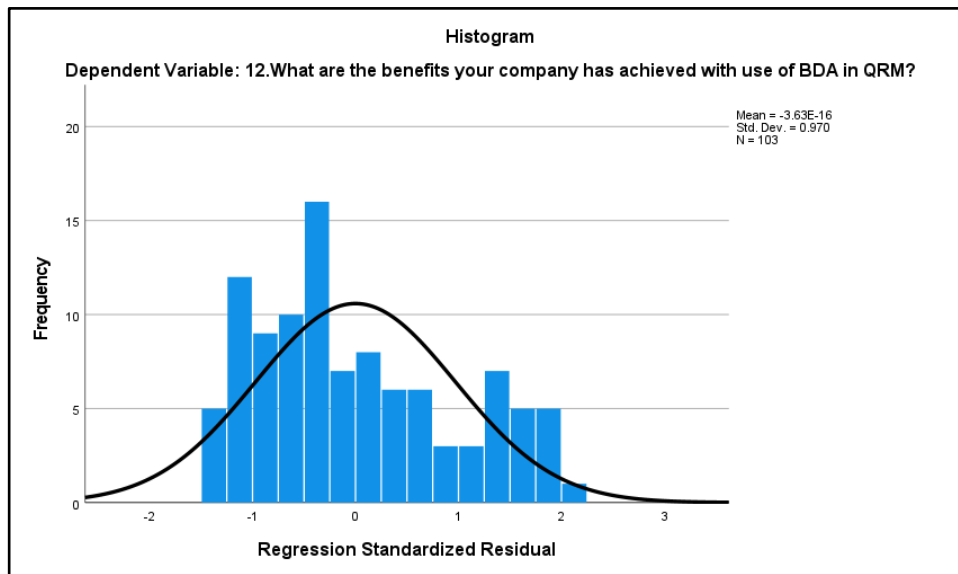


Figure 19: Descriptive, correlation and regression analysis

(Source: SPSS)

The statistical analysis presents important details about the factors that catalyse effective implementation of the Big Data Analytics in the Quality Risk Management systems of the Irish life sciences organizations. The regression model indicates a substantive association ($F=1.874$, $p=0.093$) of digital maturity, data governance and employee competency regarding BDA-assisted QRM benefits.

Digital maturity is also found to be a favourable factor ($\beta=0.137$, $p=0.376$). The higher the degree of readiness towards digitalization; the better are the opportunities to use BDA to manage quality risks (Bertello *et al.*, 2020). This implies that digital infrastructure and capabilities investments provide a successful foundation to QRM enhancement. Data governance confidence has an even more positive effect ($\beta=0.247$, $p=0.241$), reflecting the importance of sound governance arrangements in the data-driven decision-making process.

Interestingly, organizations that are already equipped with data-driven risk management tools have gaps that can be filled in terms of assimilation and strategic planning ($\beta = -0.700$, $p = 0.050$). The adjusted R - square value of 0.049 means that although these factors play a significant role in BDA success, there are other organizational issues to consider, and there is still room to optimize QRM systems through a holistic approach to digital transformation.

RQ5. Strategic Transformation Measures for Effective BDA Implementation

Descriptive Statistics			
	Mean	Std. Deviation	N
10. Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?	1.86	1.121	103
3. How will you rate your Company's Digital maturity?	2.73	1.173	103
7. How confident are you that your company will handle data governance for QRM?	2.15	.879	103
8. To what extent are your workforce equipped on the use of data-driven tools to manage risks?	2.16	.538	103
11. Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	2.04	.713	103

Figure 20: Descriptive analysis

(Source: SPSS)

Based on these statistical findings, a number of strategic implications can be deduced towards effecting the QRM in Irish life sciences organizations with the aid of BDA.

The descriptive statistics indicate a moderate confidence level concerning three key areas including digital leadership, since digital maturity is the most stressed area (mean = 2.73), indicating that companies understand the significance of technological preparedness in the context of digital maturity. Nevertheless, the mean factor of BDA importance in QRM (1.86) can be described as having much space to improve and conduct strategic knowledge building.

Correlations						
	10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?	3.How will you rate your Company's Digital maturity?	7.How confident are you that your company will handle data governance for QRM?	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	
Pearson Correlation	10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?	1.000	.225	.508	-.046	.093
	3.How will you rate your Company's Digital maturity?	.225	1.000	.410	.114	.001
	7.How confident are you that your company will handle data governance for QRM?	.508	.410	1.000	-.235	.179
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	-.046	.114	-.235	1.000	-.476
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.093	.001	.179	-.476	1.000
Sig. (1-tailed)	10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?	.	.011	<.001	.322	.176
	3.How will you rate your Company's Digital maturity?	.011	.	.000	.125	.496
	7.How confident are you that your company will handle data governance for QRM?	.000	.000	.	.008	.036
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	.322	.125	.008	.	.000
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.176	.496	.036	.000	.
N	10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?	103	103	103	103	103
	3.How will you rate your Company's Digital maturity?	103	103	103	103	103
	7.How confident are you that your company will handle data governance for QRM?	103	103	103	103	103
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	103	103	103	103	103
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	103	103	103	103	103

Figure 21: Correlation analysis

(Source: SPSS)

The correlation analysis reveals strategic relationships which are critical. The above mentioned dependence of the level of confidence in data governance on the perceived importance of BDA in QRM, which turns out to be at 0.508, illustrates that excellently built data management systems are necessary conditions of a successful implementation of BDA. Likewise, the strong positive correlation (0.410) between digital maturity and governance confidence indicates that digital maturity and governance capabilities will have to evolve in parallel.

Model Summary^b

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	Change Statistics			Sig. F Change
						F Change	df1	df2	
1	.515 ^a	.265	.235	.980	.265	8.850	4	98	<.001

a. Predictors: (Constant), 11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?, 3.How will you rate your Company's Digital maturity?, 7.How confident are you that your company will handle data governance for QRM?, 8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?

b. Dependent Variable: 10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	33.992	4	8.498	8.850	<.001 ^b
	Residual	94.105	98	.960		
	Total	128.097	102			

a. Dependent Variable: 10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?

b. Predictors: (Constant), 11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?, 3.How will you rate your Company's Digital maturity?, 7.How confident are you that your company will handle data governance for QRM?, 8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	-.159	.725		-.219	.827
	3.How will you rate your Company's Digital maturity?	.000	.093	.000	-.004	.997
	7.How confident are you that your company will handle data governance for QRM?	.667	.127	.523	5.231	<.001
	8.To what extent are your workforce equipped on the use of data-driven tools to manage risks?	.206	.214	.099	.965	.337
	11.Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?	.073	.155	.046	.468	.641

a. Dependent Variable: 10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?

Residuals Statistics ^a					
	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	.99	3.34	1.86	.577	103
Residual	-2.199	2.528	.000	.961	103
Std. Predicted Value	-1.509	2.564	.000	1.000	103
Std. Residual	-2.244	2.580	.000	.980	103

a. Dependent Variable: 10.Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?

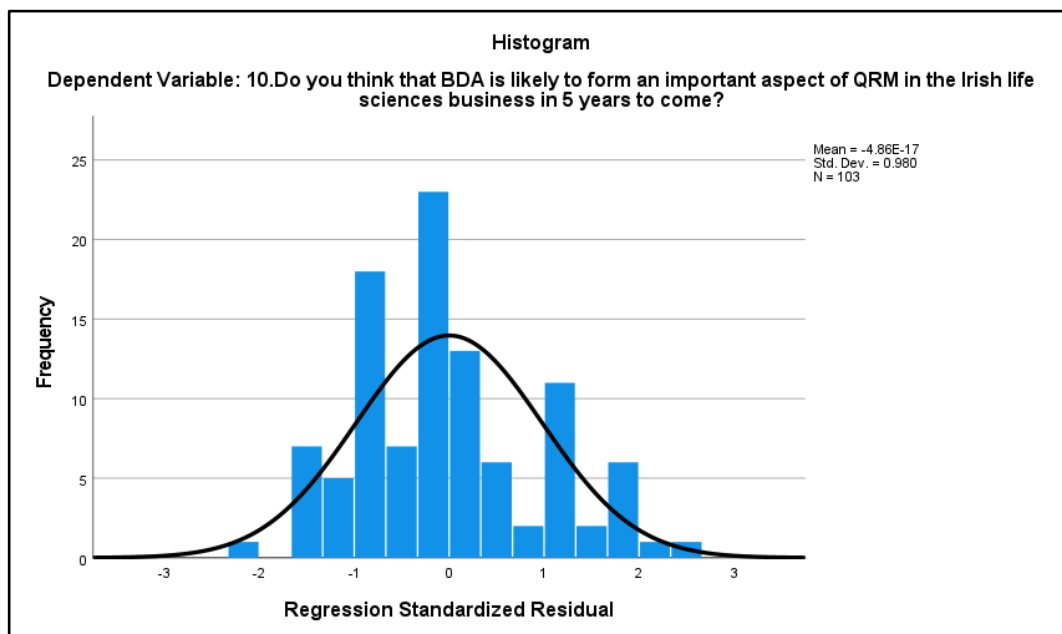


Figure 22:Regression model analysis

(Source: SPSS)

The regression model ($R^2 = 0.265$, $p < 0.001$) indicates that the data governance confidence is the largest significant predictor of BDA in QRM. Such finding underscores the importance of prioritizing strategic investments in data governance infrastructure, policies and capabilities. To be effective in their endeavour to shift QRM practices towards the implementation of BDA, organizations must work on developing more comprehensive data management frameworks, guaranteeing data quality, implementing proper data governance constructs, and developing work skills in data-driven-decision making (Vadigicherla, 2025).

4.3 Discussion

RQ1: Implementation Status of Big Data Analytics in Quality Risk Management

The analysis expresses a complex illustration of the implementation of Big Data Analytics in Quality Risk Management among Irish life sciences organizations. The high percentage of QRM companies having introduced BDA (62.1) into their QRM practices exemplifies the trend

of going beyond the initial stage of business adoption. This observation is paradoxical to the interpretation of minimal application (mean = 1.65) that was depicted in descriptive statistics, so, it is possible to note that although the implementation is taking place, its depth and sophistication differs considerably across the organizations.

The pattern of sector-specific adoptions is a very useful indicator of maturity regarding various segments. The medical device industry has a higher adoption rate of 65.9 percent, followed by pharmaceuticals (60.0) and biotechnology (43.8). Within the medical device industry, one reason may be the embrace of digital manufacturing technology earlier and its activity in Industry 4.0 projects (Lepasepp and Hurst, 2021). This trend is consistent with the focus in the literature on the Irish industrial context as a centre of global manufacturing and supply of multinational pharmaceutical and medical device firms (IDA Ireland, 2022) with attendant competitive pressures and stimulus of technological change.

The significant number of organizations stating that they are uncertain of their BDA status (27.2%) suggests that organizational awareness of and familiarity with BDA are shocking. This ambiguity, coupled with the low average awareness (1.94), indicates that several organizations might be using data analytics devices without seeing them as an official building block of their QRM system. This observation confirms that of (Shanmugam *et al.*, 2023) on the inability of technological advances to meet organizational knowledge in pharmaceutical environments.

The correlation value of 0.519 between the digital maturity and the BDA adoption measure validates the originality of having basic digital capabilities to be successful in engaging BDA adoption. Organizations with more developed digital infrastructure feel more confident about data governance ($r = 0.410$) and have better system integration ($r = 0.396$), which forms a positive feedback loop to support more advanced BDA applications. The relationship supports the need to have an overall approach to digital transformation as opposed to spot technology solutions.

RQ2: Benefits and Value Realization of BDA Integration

The benefits analysis demonstrates that there is a significant amount of value creation generated by BDA integration and that organizations procure concrete gains in several aspects of operation (El-Haddadeh *et al.*, 2021). The most important advantage improved information-based decision-making (65.7% of BDA adopters) is an essential paradigm change towards data-driven decision-making as opposed to the resolution of a crisis by intuitive technique of quality management. This change is in line with the Data-Driven Decision-Making Theory that focuses on minimizing doubt by gaining analytical knowledge (Mandinach *et al.*, 2006).

These developments in work efficiency indicate the feasible benefit that BDA contributes to production within the industry. The observation that 65.0 percent of BDA users reporting faster batch release cycles was a solid response to top-of-mind challenges in the pharmaceutical industry that involve time-to-market pressures and time to regulatory compliance. Even more importantly, the 90.9% of BDA-implementing organizations today having fewer deviations indicates that predictive analytics capacities appear to be adequately efficient at identifying and averting quality problems prior to becoming actual deviations.

The cost savings realized by a majority (53.3 percent) of BDA adopters confirm the business returns on the analytics investments, and 43.8 percent of users indicate improved audit readiness, an indication of increased regulatory compliance capability. These advantages align with the findings made by Brynjolfsson and McElheran (2016) , regarding how data-driven strategies can create improved productivity, although these numbers do not seem as significant as their 56 percent productivity growth benchmark.

The regression model that shows workforce readiness as a strong influencer of benefit realization points to a counterintuitive notion. The negative coefficient indicates that highly data-developed organizations seem to have implementation feel issues or improper use of the offered data-driven tools. This paradox conforms with the intrinsic value of the Socio-Technical Systems Theory about the equal significance of the balancing of the technological capabilities and human aspects and organizational culture (Mumford, 2006).

The moderate positive relationship that exists between perceived BDA benefits and data governance confidence ($r = 0.221$) is evidence that effective implementation restores organizational confidence in analytics capabilities. This association implies a positive self-reinforcing cycle in which initial success with BDA applications raises organizational confidence to try more advanced applications.

RQ3: Technological, Organizational, and Regulatory Obstacles

The obstacle analysis demonstrates that there are complicated interactive barriers that organizations have to navigate in the successful implementation of BDA(Dehkhodaei *et al.*, 2023). The result is a moderately positive relationship between digital maturity and data governance confidence ($r = 0.410$). The study indicates that technological development and data governance capabilities do not improve in a step-by-step process but rather develop concurrently.

The fact that the correlation between digital maturity and implementation barriers is negative, with a coefficient of -0.185, means that technologically mature organizations experience fewer barriers, which confirms the strategic importance of investments in the basis of digital maturity.

The result aligns with the importance of legacy IT systems and data silos in the literature as the major barriers to BDA adoption (Shanmugam *et al.* 2023).

Regulatory compliance has become a complex issue, as organizations strive to make the most of advanced analytics without losing data integrity, traceability, and validation demands as required in GDPR, GAMP 5, and other regulatory standards. The variability in the reported obstacles is moderate (mean = 2.92, SD = 1.226) likely as a result of different conditions surrounding the Irish life sciences sector and its maturity.

Challenges of the organizational dimension are especially complex; this is shown by the inverse relationship between data governance confidence and adequacy of workforce equipment ($r = -0.235$). This connection implies that organizations with well-developed governance regimes realize the extreme value of frequently investing in suitable technology sources about their teams, emphasizing the interrelatedness of people, process, and technology aspects (Huntjens and Kemp, 2022)

Skills gaps can also be highlighted as a long-term challenge, with the quality assurance professionals' knowledge base typically building around compliance and documentation and less in the advanced analytics area. This difficulty corresponds to Wang *et al.* (2019) forecast of organizational culture and skills-gaps as some of the major barriers to BDA integration activities in quality systems.

This adds a layer of complexity due to regulatory pressure to have strict standards of validation and documentation of complex analytics algorithms. Organizations are driven to be compliant as well as innovative, making organisations to take conservative routes which do not maximise the BDA potential realisation (Farouk *et al.*, 2025).

RQ4: Digital Maturity, Data Governance, and Employee Competency Relationships

The correlation analysis indicates great positive values that highlight the strategic value of developing the three disciplines of digital maturity, data governance, and employee competency simultaneously, and not in isolation (Mick *et al.*, 2024). The consistent relationship between digital maturity and data governance confidence ($r = 0.410$) shows that better positioned organizations with high degrees of digital maturity are more capable of establishing effective data governance.

The important correlation between the BDA application and system integration ($r = 0.396$) also demonstrates the organizational preparedness of digital infrastructure as an important factor of successful analytics application. This observation confirms the assertion of the Socio-Technical Systems Theory that both subsystems of technology implementation, technical and social subsystems need to be optimized (Mumford, 2006).

The work force competency dimension indicates significant links with both governance and integration capabilities, which point to the fact that workforce competency development is at the same level as technological competency (Elizondo and Reyes, 2023). Such synergy has multiplicative effects on the overall effectiveness of QRM, which helps to support the area of Technology Acceptance Model that underscores the usefulness and ease of use of technology in influencing technology acceptance.

Regression analysis indicates an opportunity to improve the current implementation of the data-driven risk management tools in an organization, implying that further progress can be made in such areas as approach and integration strategy. The results denote that the early adopters might be facing implementation issues that need a more subtle implementation process to achieve maximum potential (Sundaramurthy *et al.*, 2022)

The adjusted R-square of 0.049 in the model shows that although the above factors will contribute immensely to the success of BDA, there are still other organizational factors that determine the success of BDA. These intangibles were probably leadership commitment, change management success and cultural readiness to data-driven transformation.

RQ5: Strategic Transformation Measures for Effective BDA Implementation

The strategic analysis indicates that data governance confidence is the strongest predictor of BDA adoption success and highlights that effective data management systems are key pre-conditions to successful adoption. This observation is in line with that of the Risk Management Framework that stresses on the use of systematic methods in identification and management of risks (ISO 31000, ICH Q9) (Suprin *et al.*, 2019)

The high correlation between the governance confidence and the perception of BDA importance ($r = 0.508$) shows that companies with better management of their data can see the opportunities in the analytics-driven environment and leverage them. This connection implies that it is precisely investments in data governance that bring about the ability and organizational awareness to perform BDA effectively (Prakash, 2024)

The moderate confidence scores in most key areas where the digital maturity score reaches the highest (mean = 2.73) imply that organizations appreciate the role of technological preparedness as a primal but not as critical as the use of BDA in QRM settings (mean = 1.86). This knowledge gap implies that there lies huge potential in terms of strategic improvement of awareness and building capabilities.

A high explanatory power of the regression model ($R^2 = 0.265$) confirms data governance as the key leverage point of BDA transformation. It is important that organizations take in account

holistic data management tubes such as data quality assurance, data governance regulations, and staff expertise building in data programmed judgement (Achanta and Boina, 2023)

This gap in implementation-awareness must be addressed in strategic transformation. Although organizations exhibit moderate digital maturity, the low scores on BDA show that organizations should focus more on strategic communication and change management efforts to establish a commitment to transformation through analytics.

The connection of predictive and prescriptive analytics functionality with current QRM frameworks must be handled with specific regard to regulatory provisions and verification-related needs. Organizations should also build the capacity to optimize ICH Q9 risk management activities without compromising the documentation, traceability, and auditability provisions as set by the regulating agencies.

The results indicate that the implementation of BDA in QRM needs a holistic approach that takes into consideration technological, organizational, and alignment issues. Organizations that make substantial investments in data governance as a platform for a transformation in their analytics stand a better chance at realizing the predictive risk management capability that will represent the future of pharmaceutical quality management.

4.4 Summary

The results indicate that the Irish life sciences sector is at a time of crucial transition on implementing BDA in QRM and there are great chances to pioneer strategic opportunities. Although 62.1 percent of organizations have embraced BDA technologies, there is a significant variation in the level of implementation, with moderate and low scores being recorded as the average level of implementation in organizations. The analysis also reveals data governance confidence as the best predictive factor of successful adoption of BDA that explain 26.5 percent of the variance of implementation success.

The main advantages that BDA adopters expect to achieve are the improved level of data-driven decision-making (65.7%), a higher level of operational effectiveness and shorter batch release cycles (65.0%), and the reduction of the number of quality deviations (90.9%). Organizations have to deal with compound technological, organisational and regulatory challenges that must be addressed in an integrated manner. The correlation analysis indicates key interdependencies between the digital maturity, data governance capabilities, and workforce competency, and by indicating so, it suggests that successful BDA implementation needs to remain a holistic organizational-level change rather than a technological one.

Strategic implication suggests that there is a need to work out holistic data governance solutions, build capability in the workforce and develop sound system integration architecture. The moderate digital maturity levels along with low BDA awareness signify a tremendous opportunity of strategic upswing in terms of change management and ability enhancement processes. Organizations can strike a right balance between the regulatory compliance needs and innovative goals in order to maximize the transformative potential of BDA in quality risk management practices.

CHAPTER 5: CONCLUSION

5.1 Linking with objectives

The purpose of the research was to develop an in-depth insight into the following issue: the role of Big Data Analytics (BDA) in the process of cultivating better Quality Risk Management (QRM) practices in the Irish life sciences companies. Here, research objectives has been achieved by combining the information obtained in the literature and the information gained in the study.

Objective 1: To assess the extent of implementation of BDA in QRM practice within the Irish lifestyle company

The literature indicated that the adoption of BDA in the world is rising, but not uniform in well-regulated industries such as the life sciences industry, caused by issues related to culture, infrastructure, and compliance (Clancy and O'Rourke, 2021; Wang *et al.*, 2018). The survey results justified such uneven implementations within Ireland. Although a majority of firms reported adoption to some degree of BDA in QRM, mean implementation outcomes (1.65 on a 3-point scale) were characterised by low levels of both depth and sophistication. There was a difference per sector, with medical devices enjoying a greater rate of adoption (65.9%) than the pharmaceutical industry (60.0%) and biotechnology (43.8%). In addition, 27.2% of the respondents communicated indecisiveness in regard to adoption, and this is a gap in organisational awareness. This is compliant with the evidence provided in the literature that awareness and acceptance are always low in comparison to the availability of technologies (Shanmugam *et al.*, 2023).

Objective 2: To evaluate the benefits and value-added outcomes of integrating BDA into QRM framework

The overview of the literature pointed out that BDA increases predictive risk identification, mitigates deviations, helps to be regulatory compliant, and has data-driven decision-making (Rane *et al.*, 2024; Mulholland, 2024). Proven by Pull-to-Determine Finding: 65.7 % of BDA adapters noted their decision-making had been enhanced, 65.0 % noted accelerated batch release activities, and 90.9 % observed decreased deviations. Cost savings (53.3%) and greater audit readiness (43.8%) were other confirmations of BDA delivering real value. Regression analysis categorically determined workforce readiness and digital preparedness as two main factors that had significant impacts on benefit realisation. Therefore, BDA provides operational and compliance advantages that have been quantified as long as BDA is characterised by effective governance and proficiency.

Objective 3: To identify and analyse the key technological, organisational, and regulatory barriers hindering adoption

In the literature, legacy IT, data silos, talent shortage, and rigid data integrity concerns have been identified (ICH, 2022; Sivarajah *et al.*, 2017). Such findings were supported by the fact that those organisations that were less digitally mature had a higher barrier and those that were more mature had a lower barrier. The -0.185 score of the negative correlation that exists between digital maturity and perceived barriers indicated that adoption challenges are alleviated by investing in infrastructure. Organisational obstacles were as follows: low competency of the workforce and change initiatives, with many QA professionals having insufficient skills in advanced analytics. Existential barriers were also present: GDPR and GAMP 5 requirements made validation of advanced analytics more cumbersome, causing companies to implement conservative practices. This supported the fact in the literature that there are two-fold challenges of innovation and compliance (Thanasas *et al.*, 2025).

Objective 4: To examine the influence of digital maturity, data governance, and employee competency on BDA-assisted QRM effectiveness

The literature further pointed out that these three dimensions are to be developed simultaneously in order to achieve success (Mikalef *et al.*, 2020; Mumford, 2006). This was strongly supported by the findings as digital maturity showed a positive correlation with BDA adoption (0.519) and with confidence in governance (0.410). Authentic qualifications of workers were also strongly connected to information management and data integration illustrates that workforce training accompanies investment in infrastructure. Regression models showed that digital maturity/governance increased adoption, but having workforce readiness directly influenced the realisation of benefits. This also goes hand in hand with the Socio-Technical System Theory that upholds the need to balance out technical capacity and human capability.

Objective 5: To propose strategic measures for promoting adoption, compliance, and efficient utilisation of BDM in QRM

It was clarified in the literature that strong governance models, digital transformation strategies, and congruence with ICH Q9 (R2) are critical (ICH, 2022). Of the findings, data governance confidence was predicted as the most significant factor in adoption success ($R^2 = 0.265$, $p < 0.001$). Some of the strategic actions suggested are the enhancement of data governance structures, investment in training of the workforce, enhancement of cross-system integration, and development of a culture of decision-making based on analytics. Organisations should also

kick-start the management of changes to create awareness and commitment, to fill the gap between moderate digital maturity and low awareness.

5.2 Future Scope

Although this study has undertaken a comprehensive examination, there exists room to develop it in other directions. To begin with, longitudinal studies would help future researchers to follow the process of BDA adoption and maturity over a given arc of time, and thus understand how digital transformation is pursued among various parts of the Irish life sciences sector. Second, a comparative study with other nations might identify whether the challenges and opportunities that Ireland faces are peculiar to it or occur worldwide in terms of pharmaceutical and medical device production. Third, it could also broadly address clinical and supply chain opportunities of applying BDA to gain further knowledge on quality and risk management outside of the manufacturing processes.

The other emerging area of interest would be the use of emerging technologies like artificial intelligence (AI), blockchain and digital twins to supplement BDA in QRM. These technologies would enhance the integrity of the data, its traceability, and regulatory consciousness. Further research can also centre on aspects of culture and behaviour, addressing how commitment to leadership, change management and risk culture information can influence the success of BDA adoption. Lastly, a stronger focus on the regulatory side should be provided with a partnership work with organisations such as EMA and HPRA, as it can help to better align innovation with compliance, thus taking them to the policy-level recommendations.

5.3 Recommendation

Based on findings and the literature, some recommendations are derived:

1. Empower data governance structures

- Create central validated systems that maintain traceability, integrity and auditability of data.
- Navigate according to ICH Q9 (R2) and GDPR in order to generate good graces of the regulators.

2. Invest in the upskilling of the workforce

- Conduct training in analytics, machine learning and data-driven decision making to QA, QC and risk management staff.

- Promote interdisciplinary collaboration between quality professionals and data scientists.

3. Advanced electronic support and combination

- Integrate BDA tools with MES, LIMS, and ERP systems, and replace existing IT systems with legacy practices.
- Design digital platforms that can scale and support cross-functional analytics and predictive risk management.

4. Promote organisational change and risk culture

- Manage change efforts to create awareness and dedication to the adoption of BDA.
- Build a culture of proactive, evidence-based, analytics-driven risk.

5. Strategy alignment, policy advocacy

- Provide an incentive to align corporate digital strategies with national plans, e.g. Industry 4.0 strategy in Ireland.
- Cooperate with regulatory agencies to create policies that enhance the balance between innovation and compliance.

4. Pilot archives and lifelong learning

- Use pilot projects in a controlled environment in order to demonstrate the advantages of using BDA prior to implementation on a large scale.
- Utilise the incorporation of continuous feedback loops in the enhancement of QRM models and analytic strategies.

A combination of these recommendations will ensure Irish life sciences players have a comprehensive framework to make the most of BDA in QRM, without sacrificing compliance or competitiveness.

5.4 Conclusion

This paper has assessed the potential of Big Data Analytics to enable Quality Risk Management in the Irish life sciences industry. The results indicate that firms to a larger degree have implemented BDA to some degree, although the depth is low, with gaps existing in awareness, governance and capability of its workforce. However, there are definite advantages, including better decision making, fewer deviations, quicker release of batches and enhanced regulatory compliance, that confirm the value that BDA holds as a strategy. Obstacles to adoption remain in the form of legacy central IT systems, lack of skills, and regulatory complexity, but digital

maturity, effective data governance, and the competency of workforces are the most significant factors of adoption success.

The gap between potential and practice needs to be bridged by strategic measures in the areas of governance, infrastructure, skills and cultural transformation. With the organisation of these measures, Irish life sciences companies will be able to transform to predictive, preventive, and data-driven QRMs, which will guarantee regulatory compliance and facilitate operational excellence

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APPENDICES



Ethics Application & Declaration Form

DISSERTATION TITLE: Enhancing Quality Risk Management in Irish Life Sciences through Big Data Analytics: A Strategic Analysis

RESEARCHER'S NAME: Nandhana Padmakumar

PROGRAMME OF STUDY: MSc Digital Transformation

SUPERVISOR'S NAME: Nicola Rice

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: 

DATE:

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required:

Yes No

SUPERVISOR SIGNATURE: 

DATE: 7/9/25

For Ethics Committee (if required):

Ethics Committee Approval Given:

Yes

No

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research *[300 words maximum/ use literature review findings to guide]*

This research is aimed at investigating the use of Big Data Analytics (BDA) in Quality Risk Management (QRM) frameworks within the Irish life sciences sector. The proposed study will explore the role of the BDA tools and technologies in proactive risk identification, increasing compliance and minimising the number and the level of quality deviations.

Recent studies indicate that BDA can help in process QRM development by assisting risk identification to occur continuously and enhance decision-making via pattern recognition and predictive insights (Williamson and Prybutok, 2024). The obstacles in the Irish setting are also enormous; among them include organisational resistance, fragmented legacy systems, regulatory uncertainty and skills gaps (Basile *et al.*, 2024).

Objectives:

- To investigate the current implementation of Quality Risk Management (QRM) systems in Irish life sciences companies with regard to the Big Data Analytics tools and technologies, including machine learning, data lakes, and real-time monitoring.
- To analyze the success of BDA in mitigating deviations, audit preparedness and improvement of batch release schedules of large pharmaceutical multinationals and smaller biotech companies in Ireland.
- To identify the main technological, organisational, and regulatory obstacles to the broader implementation of Big Data Analytics in QRM models based on ICH Q9 recommendations.
- To determine the impact of digital maturity, data governance and level of worker skills on the success or failure of BDA integration within quality processes.
- To propose strategic recommendations, such as training programs, data infrastructure enhancements, and regulatory involvement channels, that may help in the effective and compliance-driven adoption of Big Data Analytics by QRM in Irish life sciences industry.

1.2 Research methodology: *[300 words maximum/ detail how you will acquire your primary data (focus groups/interviews/online surveys etc). Proposed questions for questionnaires and/or interviews must be included in the appendix].*

In this paper, a quantitative research approach will be adopted with the positivist paradigm used to collect and analyse quantifiable data regarding the applicability of Big Data Analytics (BDA) in Quality Risk Management (QRM) within Irish life sciences organisations. An online survey is chosen because it allows gathering statistically relevant results of a diverse and geographically distributed survey of professionals operating in the fields of quality assurance, compliance, production, regulatory affairs areas, data analytics and digital transformation. This survey will be conducted using Google Forms, Qualtrics or SurveyMonkey which will guarantee the flexibility of access and data security

Variables that are to be measured by using close-ended Likert scale questions, multiple-choice, and ranking-type question in the questionnaire include:

- Present-day application of BDA in QRM
- Perceived advantages
- Organisational and regulatory obstacles
- Levels of interconnection to other systems (e.g. MES, ERP)
- Human-automation interaction in decision-making

Non-probability purposive sampling will be used to select the participants to make sure that the respondents with the relevant experiences are included in the research results. The survey will be sent through LinkedIn, the industry mailing lists, and emails to known individuals working in the life sciences field. The inclusion criteria concern the participants being directly involved in or knowing about QRM and digital initiatives at their companies. This method will assist in relevancy and quality in responses. The aim would be to get around 150 valid responses.

A pilot test will be performed in 3-5 target population professionals to test the clarity of the phrasing, adequacy of questions and survey continuity. The data will be analysed through descriptive statistics and inferential statistics using JASP or SPSS, where applicable, through chi-square tests, correlation analysis, and ANOVA. To ensure the internal reliability of Likert-scale items, Cronbach alpha will be employed. All information will be provided in tabular and graphical forms.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about

the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

- 3.1. If your ethics relates to **Subject Matter**, outline your action plan to work around any sensitive issues.
- 3.2. If your ethics relates to **Research Procedures**, outline your action plan to deal with possible ethical issues in your research procedures.
- 3.3. If your ethics relates to **Participants**, outline how you will protect vulnerable persons or those that do not have English as their first language.

Even though there were no ethical issues considered as high-risk regarding Section 2, this study does not disregard the significance of ethical standards to be reached during the study. It is a project including an anonymous online survey and it will be accomplished by asking professionals voluntarily to take part in non-sensitive work-related context.

Low-risk considerations have been covered as follows:

- The study participants will be explicitly explained the purpose of the study, the use of their data, and the rights as respondents at the beginning of the survey
- The consent and the right to withdraw will be explained to participants before the submission of the survey.
- The anonymity and confidentiality will be followed.
- All data will be also managed in compliance with GDPR regulations and stored on a password-protected drive and will be destroyed once the dissertation is graded and reviewed.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study *[Do not provide names except where it is deemed impossible to conceal identity].*

The participants will include professionals who are engaged in quality assurance/ compliance/ data analytics or digital transformation in Irish based pharmaceutical or biotechnology businesses. They are selected because of their background in QRM processes and data-driven projects.

4.2 How do you plan to gain access to/contact/approach your participant(s).

The survey will be conducted through SurveyMonkey ,Google Forms or Qualtrics. The professional platforms and networks such as LinkedIn, industry mailing lists and direct email invitations will be used to reach the participants. The outreach messages will have a short description of the purpose of the research, about the target participants , and a link to the online survey.. The survey will be voluntary and anonymous.

To address informed consent in a proper way, the opening page of an online survey will contain a short Participant Information Letter (PIL). This will make it clear what the study is about, what will be required to participate (including anonymity and time) and that the participation is voluntary and that they have a right to withdraw any time. It will also summarize data protection in accordance with GDPR and include contact information indicating the researcher and the academic supervisor. Prior to proceeding with the survey the participants will be signed to consent.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 Participant Information Letter (PIL) for participants

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the

beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 Informed Consent Form (ICF) for participants

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

No: my research study involves an online survey only and/or does not require signed consent

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/>].

The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Data will be saved safely in a password-protected cloud drive and uploaded to the Griffith Moodle Primary Data Folder when submitting. All data will be anonymised and can only be retained until the dissertation is graded and externally reviewed after which it will be destroyed. At all times, GDPR compliance and ethics will be adhered to.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 Non-Disclosure Agreement (NDA)

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 Student consent

If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 Viva Recording

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc (<i>can be in draft form</i>)	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE:

SECTION 10: APPENDIX

Hi,

This survey will be submitted as an MSc dissertation report on the research on the way Big data Analytics (BDA) is implemented in the domain of Quality Risk Management (QRM) in the Irish life sciences industry, which consists of pharmaceutical, biotechnology, and medical device companies. The purpose is to investigate the present situation, issues, and potential strategies surrounding the incorporation of data-driven technologies including machine learning, data lakes or real-time analytics to enhance compliance, deviation management, and audit preparedness.

Professionals working in the field of quality assurance, compliance, data analytics, digital transformation, production, and regulatory affairs are therefore a significant contributor to all these changes and beneficiaries. The information you will provide will be used to construct a grounded and informative image of how BDA is changing and revamping QRM practices in Ireland and actions that can be taken to promote sound and compliant practices.

The answers will remain strictly anonymous and confidential. No identifiable information will be used including names of individuals or businesses. Information collected under this survey will be stored safely and only used in academic purposes to be in line with GDPR.

The participation is voluntary.

By continuing, you confirm that you are a present or former professional who worked or is still working in the Irish life sciences sector and that you leave your consent to participate in this study.

1. What is your current area of expertise?

- a) Quality Control/ Assurance
- b) Production/Operations
- c) Digital Transformation
- d) Data Analytics/IT
- e) Others (Please specify):

2. What type of company do you work in?

- a) Pharmaceutical
- b) Medical Device
- c) Biotechnology
- d) Others (Please specify):

3. How will you rate your Company's Digital maturity?

- a) Very low
- b) Low
- c) Moderate
- d) Very high
- e) High

4. Does your company apply Big Data Analytics (BDA) to Quality Risk Management (QRM)?

- a) Yes
- b) No
- c) Not sure

5. If Yes, which BDA tools are applied in QRM? (Select all that apply)

- a) Real-time monitoring
- b) Machine Learning
- c) Predictive Modelling
- d) Others (Please specify):

6. What do you consider as the main obstacles to the implementation of BDA in your QRM processes?

- a) Cost of implementation
- b) Data quality and integration issues
- c) Lack of technical expertise
- d) Legacy IT systems
- e) No challenges
- f) Others(Please specify):

7. How confident are you that your company will handle data governance for QRM?

- a) Not confident
- b) Moderately confident
- c) Very confident
- d) Extremely confident

8. To what extent are your workforce equipped on the use of data-driven tools to manage risks?

- a) Not trained
- b) Basic training
- c) Advanced training
- d) Not applicable

9. Which will be the most strategic improvements needed to your QRM approach in your organisation? (Select 3 answers)

- a) Better data governance models
- b) Access to real-time data dashboards
- c) BDA tools training
- d) Cross-functional collaboration
- e) More integration of quality systems
- f) Case studies
- g) Others(Please specify):

10. Do you think that BDA is likely to form an important aspect of QRM in the Irish life sciences business in 5 years to come?

- 1. Very unlikely
- 2. Unlikely
- 3. Neutral
- 4. Likely
- 5. Very likely

11. Is your QRM integrated with other systems (e.g. MES, LIMS, ERP)?

- a) Yes, fully integrated

- b) Partially integrated
- c) Not integrated
- d) Not sure

12. What are the benefits your company has achieved with use of BDA in QRM?

- a) Data driven decision-making
- b) Faster batch release
- c) Better audit readiness
- d) Fewer deviations
- e) Cost savings in quality management
- f) No measurable benefits
- g) Others (Please specify):

13. Feel free to comment or share other experiences with respect to Big Data Analytics and Quality Risk Management:



Participant Information Letter

Enhancing Quality Risk Management in Irish Life Sciences through Big Data Analytics: A Strategic Analysis

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Nandhana Padmakumar and I am a student in the MSc in Digital Transformation programme in Griffith College, Dublin. I am conducting this dissertation as part of my degree requirements. This research is in order to determine how life sciences companies in Ireland apply Big Data Analytics (BDA) to enhance their Quality Risk Management (QRM) process. In particular, we want to know how tools such as machine learning, data lakes and real-time monitoring can be used to reduce quality problems, facilitate compliance, and accelerate batch release within pharmaceutical and biotech companies.

WHAT WOULD TAKING PART INVOLVE?

If you consent to take part, you will be requested to fill short online survey form. The survey is estimated to last about 10-15 min. It will have the questions on multiple choice, Likert-scale and ranking format regarding your experience or opinion on use of BDA in QRM.

There are no interviews and follow-ups that are necessary unless mutually accepted. The answers will be confidential. Audio recordings of any kind will not be registered and no personal identifiers will be captured.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

Your invitation is based on the fact that you are a professional within the quality assurance, compliance, data analytics, digital transformation, operations or production fields of the Irish life sciences sector. Your experience is relevant to the research being conducted directly and will assist us in gaining further insights about real-life applications and difficulties about the introduction of BDA in QRM.

DO YOU HAVE TO TAKE PART?

- It is entirely voluntary.
- You can choose to stay out without any penalty.
- You are allowed to skip over any question.
- You may also leave whenever you want and quit the study without explanation.
- After the initiation, should you decide to withdraw, then you can contact me at nandhana.padmakumar@student.griffith.ie and your data will be deleted as long as it is identifiable.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Taking part poses no known risks. No sensitive and personal information will be requested in the survey. Your answers will be anonymous.

Although it does not directly give you any benefit, your feedback could inform how Big data analytics can be used to better understand life science, and the future of research and policy into risk management and compliance.

WILL TAKING PART BE CONFIDENTIAL?

All answers are going to remain anonymous and confidential. There will be no records of names, emails, or the company names. Any information that you submit will be collected along with that of others in a manner which will not identify you. Confidentiality would be breached only when it is out of rare occurrence when your response reveals real danger of harm to oneself and others or when it reveals serious criminal activity.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

- All digital survey data, and signed consent forms (where applicable) will be stored, securely:
- The data will be stored in an encrypted password-protected computer which only the researcher will have access.
- Raw data will not be shared with anybody.
- Any identifiable data will be erase after the award of degree.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The findings of this will be applied to address the needs of a dissertation within the MSc in Digital Transformation programme . The final dissertation will be submitted to the college after completion, and will made possibly be available in the college library as an academic reference. Further, the results can be reported to some scientific or professional forums like conferences, seminars, or research meetings. It is also possible that the research might end up being published on academic journals that would involve peer-reviewing or to appear in academic databases which would help in future debates on the incorporation of Big Data Analytics in Quality Risk Management in the life sciences industry. Maximum confidentiality will be guaranteed in every situation- no participant or individual, no company will be associated with the results in the course of publication or sharing of the results. Privacy will be guaranteed by anonymising all data provided, in order to correspond with ethical standards of research.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

If you have questions or want more information, please contact:

Researcher: Nandhana Padmakumar

Email: nandhana.padmakumar@student.griffith.ie

Academic Supervisor: Nicola Rice

Email: nicola.rice@griffith.ie

Griffith College ,Dublin

Thank you