WHITE PAPER

Information Management in Life Sciences:

Data Responsibility and Opportunity

A Survey of the Current State of Information Management in the Pharmaceutical Industry

nnit
IT for life sciences

Contents

About the Study

The purpose of the study is to gain a better understanding of the current state of Information Management in Drug Development. The outset is an exploration of the extent to which 'compliance' and the pursuit of 'business advantages' drive the adoption of Information Management.

After an era of 'eClinical', 'Paperless Clinical Trials' and 'Moving to the Cloud', the pharmaceutical industry is now facing 'Big Data' and 'Information Management'. Both hold promises in an industry where data and the ability to analyse data is a vital asset in both the development and post-marketing of pharmaceutical products.

This study will investigate and discuss some of the trends related to Information Management in the pharmaceutical industry:

- To what extent do pharmaceutical companies prioritise their business goals and the supporting factors in pursuing these?
- How do pharmaceutical companies currently utilise data and what benefits do they expect from Information Management?
- How are pharmaceutical companies addressing Information Management in terms of budget, time and resources?

Facts

- The survey was conducted online in the spring of 2013.
- Twenty-seven respondents participated in the survey representing 22 pharmaceutical companies.
- Sixty-two per cent of the respondents represent the Director to the Vice President level.
- NNIT customers as well as non-customers are represented.
- The data represented in this white paper is aggregated.

Source

NNIT Drug Development Information Management Survey, spring 2013, N=27.

About NNIT

NNIT is a full-service IT consultancy specialising in using IT to overcome the complex challenges inherent in the life sciences industry. NNIT delivers integrated IT services and solutions that support the development, testing, production and marketing of drugs and medical devices in full compliance with applicable legislation. With a complete range of offerings from consultancy to development and operations, NNIT can help optimise business processes to reduce costs, free up resources and shorten the time to market.

Contact

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Information Management in Drug Development

Bringing a molecule from its early stage of development to the market is associated with a vast myriad of challenges, each affecting specific phases of the development process. The process is further complicated by the highly regulated environment that pharmaceutical companies must navigate while leveraging the final product return on investment.

Throughout the process there is an obligation to collect, analyse and report data in a manner that supports sound decision making. Equally important is the ability to evaluate and prioritise projects in light of the financial implications associated with specific project phases, when moving from phase II to phase III, for example.

Information Management, as a discipline, holds a holistic perspective on data and the way the organisation manages data and includes a view on IT infrastructure, analytical skills, data quality, data processing and data accessibility. It encompasses a strategic framework for how the organisation and potential partners, Contract Research Organisations (CRO), for instance, collect, distribute, report and analyse data.

Due to the nature of the legislative environment, Information Management in a pharmaceutical context is, to a certain extent, dictated by external regulatory requirements. The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are gradually introducing requirements for the adaptation of submission formats (e.g., CDISC, xEVMPD and ISO IDMP). Pharmaceutical companies are, in turn, expected to adapt their data to these requirements, further necessitating company-wide control, accessibility and adequate business processes supporting this.

While compliance is a prerequisite, harvesting genuine business advantages requires a more opportunistic approach to data – there is a difference between being in the game and changing the game. The ability to make the most of data, by reusing populations, analysing the margins to gain new insights, building new models and processing data more quickly, for instance, is a competitive parameter that can be enhanced by Information Management. This requires system integration, data standardisation and process standardisation.

Priorities Within Drug Development

The ability to prioritise as part of pharmaceutical drug development is essential in a market that is increasingly influenced by fierce competition across therapeutic areas. This is even more pronounced given the staggering time span and phases a new molecular entity (NME) must surpass to reach regulatory approval and subsequent marketing. Paving the road are multibillion dollar investments, extensive non-clinical and clinical studies and finally, market, shareholder and patient expectations.

In light of this, it is not surprising that respondents, to a large degree, indicate that both 'Shortening time to market' & 'Increasing pipeline to market' are the predominant priorities *(see figure 1).*

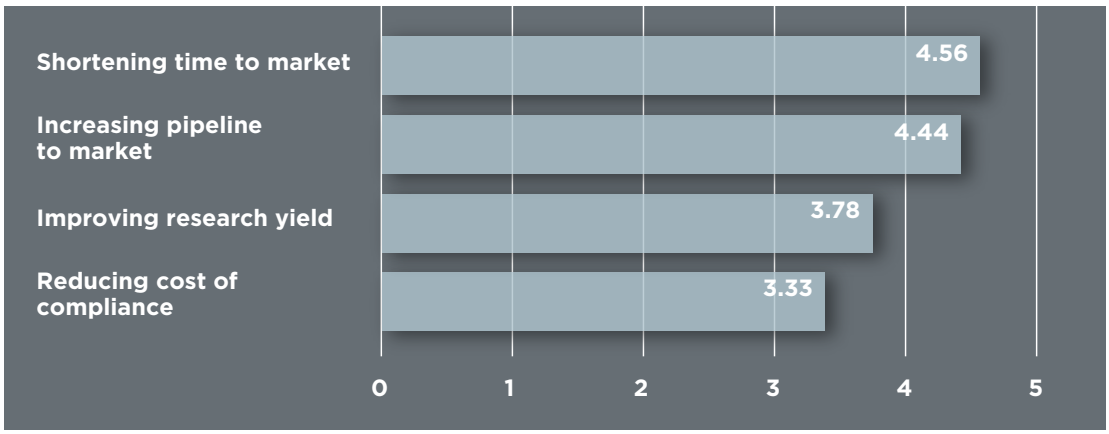
Pharmaceutical companies that are able to continuously improve business processes and optimise throughout business areas may end up reaping the benefits by fully exploiting patent, regulatory and data exclusivity.

Furthermore, this is important in an industry that is known for spending unprecedented amounts of money and resources on R&D. The ability to shorten the time to market may influence the R&D pipeline by ensuring a steady revenue flow.

Of particular interest is the fact that reducing the cost of compliance has the lowest priority among the respondents. The highly regulated pharmaceutical environment requires a basic level of compliance, dictated by internal quality management (SOPs, guidelines, instructions, etc.), as well as external requirements (e.g., GCP, GMP and ICH).

FIGURE 1

On a scale of 1 to 5, where 5 is very important, rate the following priorities for your business.

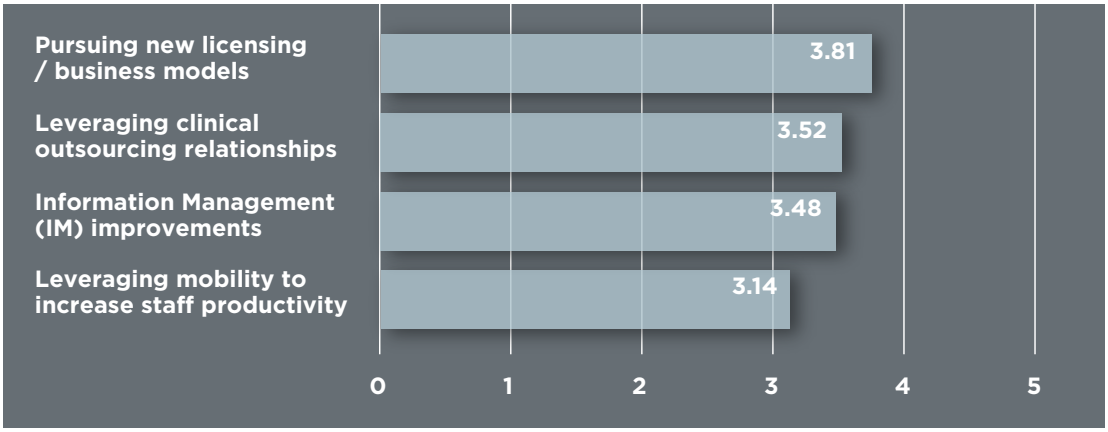


Compliance is a prerequisite, regardless of the cost, and reducing the overall cost associated with compliance is, as indicated in this white paper, not perceived as an area of high priority. This supports the notion that compliance has become embedded within the organisation as a foundation for all developmental activities.

The money spent on compliance is primarily spent on process optimisation, as is indicated by 88.9 %. Process optimisation may contribute to giving companies a head start over competitors by making the organisation more streamlined, providing operational efficiencies and enhancing the ability to drive the drug development forward quickly.

FIGURE 2

Indicate how you pursue your priority goals and to what extent you prioritise each effort.



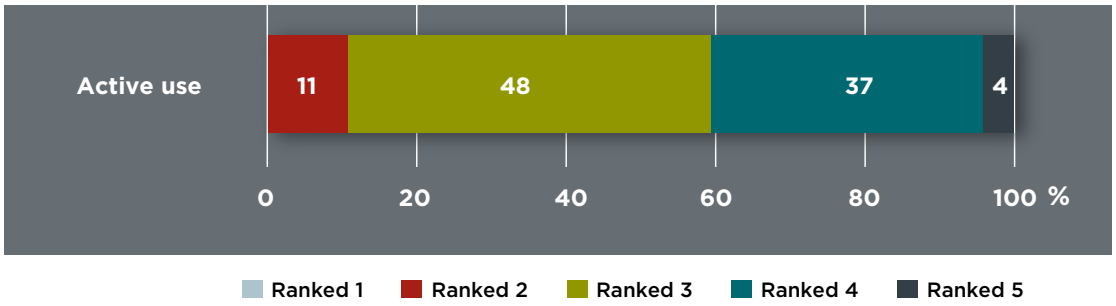
'Information Management' is, as indicated in *figure 2*, one of the measures that companies deploy to pursue their individual priority goals. However, the remaining factors (e.g., 'Pursuing new licensing/ business models') all share some of the characteristics of Information Management. Data format, accessibility, reporting and harmonisation are all areas that may be aided by proper Information Management and, in turn, support the ability to achieve priority goals.

Why Information Management?

Evaluating the current use of information within the individual organisation may give some indication as to the potential of Information Management. Interestingly, 41% respond that they use their current information actively to a high or very high extent, of which only 3.7% say they exploit data to a very high degree *(see figure 3).* The majority of the respondents perceive that information may be used more actively within their organisation.

FIGURE 3

Please indicate to which degree you use your existing information actively, where 5 indicates a very high degree.

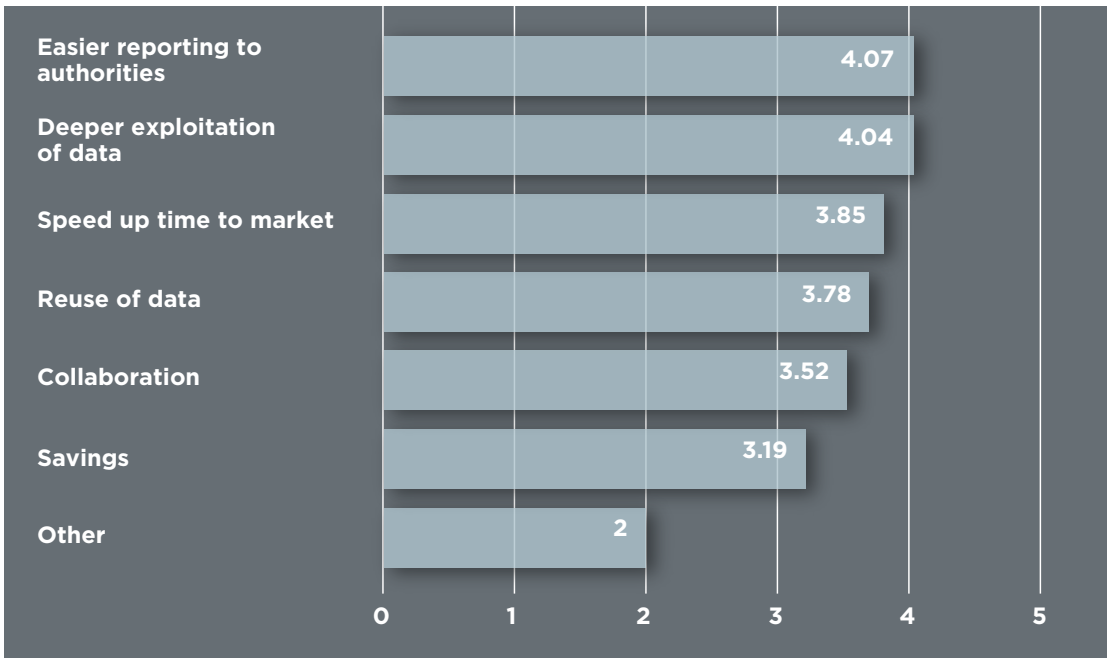


The benefits expected by introduction of Information Management within an organisation are diverse. As illustrated in *figure 4*, 'Easier reporting to authorities' and 'Deeper exploitation of data' are areas where most respondents expect to reap the benefits of Information Management. The two objectives outline the scope of Information Management in Drug Development: 'compliance' and 'business opportunities' or a 'defensive' and an 'opportunistic' approach to data.

Health authorities increasingly expect to obtain data from pharmaceutical companies to ensure and safeguard public health, as well as overall company compliance. This is pronounced throughout the drug development life cycle, ranging from the first CTA submission to large scale post-marketing safety surveillance. The potential to optimise these resource-demanding processes while exploiting data could prove beneficial for companies that aim to fulfil their individual priorities.

FIGURE 4

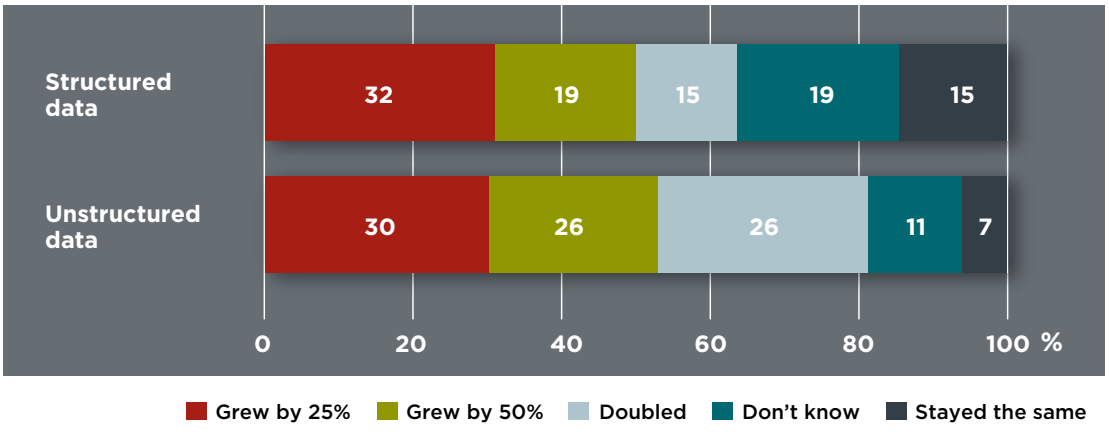
On a scale from 1 to 5, where 1 is not at all, to which extent do you prioritise the following benefits from Information Management?



In light of the character of benefits sought from Information Management, it is surprising that only 44% of the respondents say they have an Information Management strategy. This indicates that the concept of Information Management is still immature within the majority of companies.

FIGURE 5

Thinking about the volume of data in your drug development environment, how has it grown in the past year?



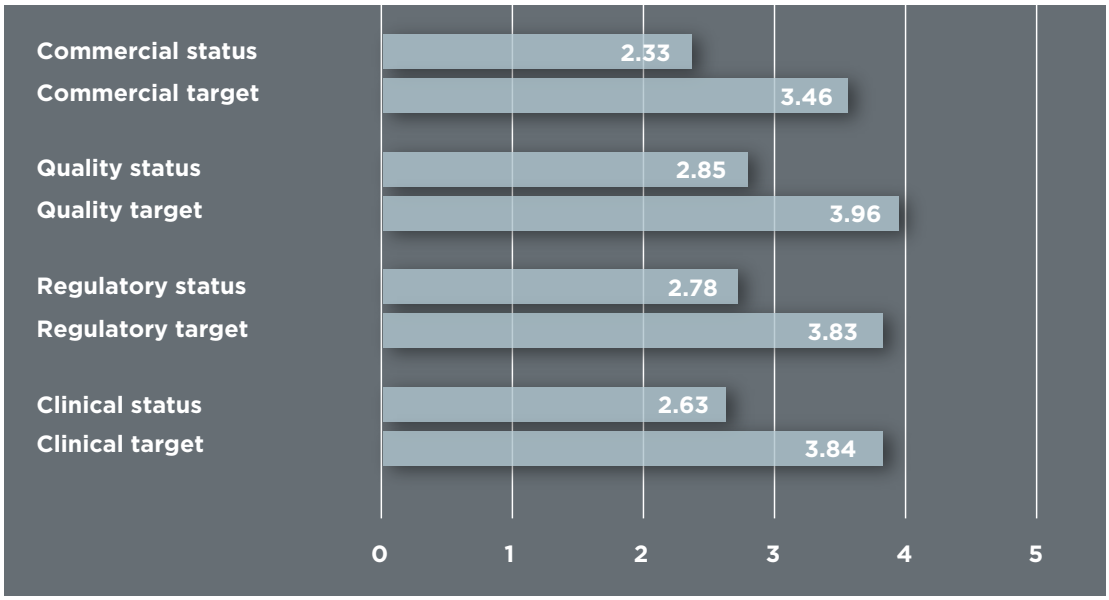
As illustrated in *figure 5* on the previous page, a significant proportion of the data growth is due to the rise of unstructured data. The survey shows that respondents experience that unstructured data is outpacing structured data, though one in five respondents could not quantify the data growth rates. This is a potential concern as it indicates a lack of overview or no specific attention directed towards the data growth rate.

Data visibility is a good marker for the overall maturity of Information Management. When respondents were asked about targets and the current state for data visibility, responses show that there is a gap between targets and the reality *(see figure 6).* Although the targets are somewhat modest, none of the data visibility targets are met within the commercial area, quality, the regulatory field or within the clinical space.

The quality target scores highest, while the biggest gap between target and current status is in the clinical space. Poor data visibility impacts the efficiency and the performance negatively and is an important issue to address. The modest target within the regulatory area is a bit surprising, as lack of visibility here may lead to non-compliance and put the company in a difficult situation, if the data is not in complete control. The gap between status and target in the clinical area is also a cause for concern, and may reflect general difficulties in introducing a standard for capturing and managing data or may be due to the fact that data to a large degree resides in silos.

FIGURE 6

To what degree do you have data visibility across your organisation's functions? 1 is low visibility and 5 is complete transparency.

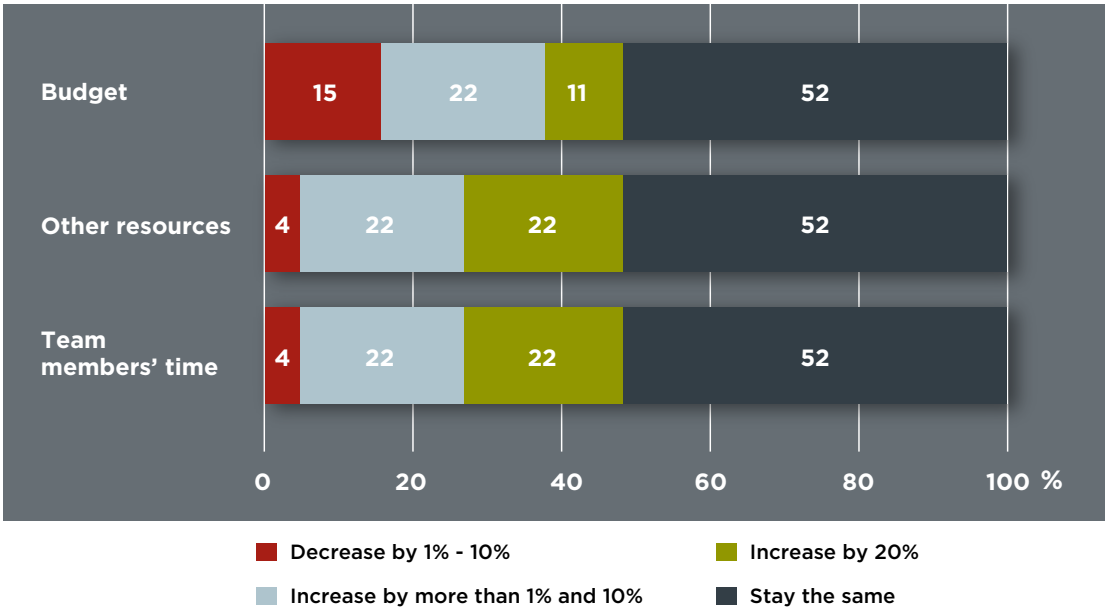


Organisational Considerations

Pharmaceutical companies that venture to engage in Information Management may acknowledge that implementation and full exploitation of the business benefits are associated with both budgetary and resource considerations. This survey found that 15% of the respondents indicated that the budget associated with data management would be decreased between 1.0% and 20% between 2012 and 2013 *(see figure 7)*. On the other end of the spectrum, 33% expect budgetary increases while the majority (52%) expect that the budget will remain the same. 'Resources' and 'Team members' time' seems to mirror one another in the survey.

FIGURE 7

Thinking about your team's time, resources and explicit budget for data management, how do you expect them to change between 2012 and 2013?

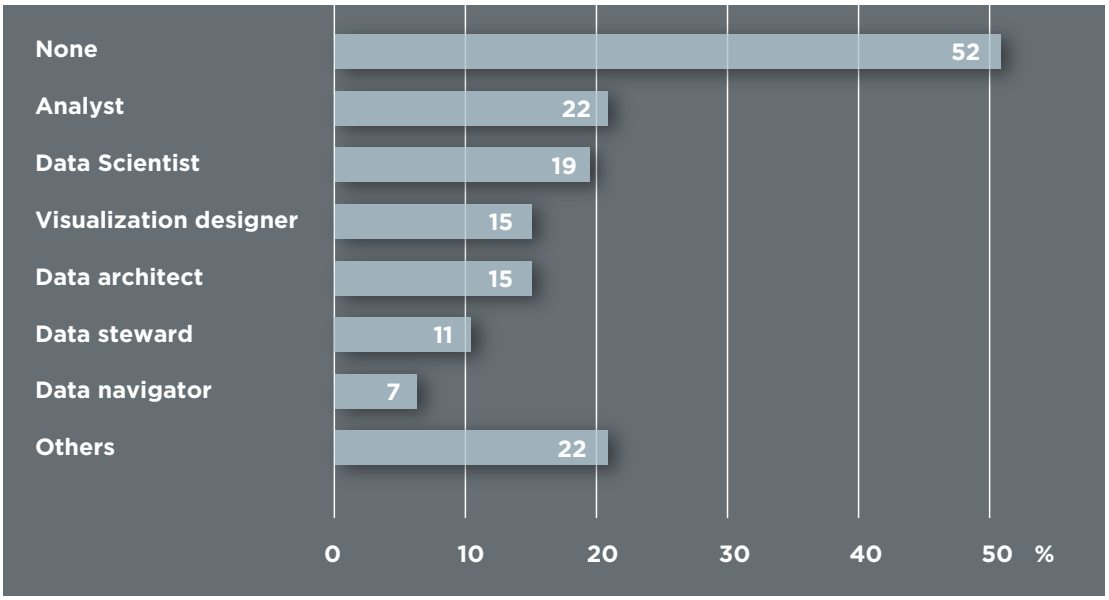


The majority of the respondents (>50%) have not yet created new roles to focus on data exploitation initiatives *(see figure 8 on page 12)*. This indicates that data responsibility is added on top of existing roles and that Information Management initiatives are not supported by actual implementation in the line of business. This is a potential concern. In particular, the unstructured data is a relatively new path that allows researchers to perform new types of queries. However, unstructured data is difficult to analyse as it does not fit into a relational database. So, in order to be able to extract value from unstructured data, semantic and image mining capabilities will be required. Without these competencies, unstructured data will simply remain dark matter in the database, together with a vast majority of the traditional, structured data.

Information Management can only successfully become embedded within the organisation if the strategic initiatives are supported by the acknowledgement that data is a vital company asset that must be supported by adequate organisational resources and competencies.

FIGURE 8

Given the increase of data and the importance bestowed to data, what new roles have you created?



Analytical Capability is Key

Data is the one real asset in a pharmaceutical company. So what does it take to unlock the value of data? The ability to analyse data touches upon three basic components:

- Data quality
- Infrastructure
- Competencies

If we look at the challenges, as assessed by the respondents, there is still some work ahead. Access to data is a major concern. Sixty-seven per cent indicate that this is a challenge to a high or very high degree. Fifty-two per cent indicate that the amount of data is a challenge in itself, and lack of data management competencies also poses a significant challenge. Consequently, it is no wonder that only 27% say that poor data quality is a challenge when generating value from data. It could be concluded that a lot of the data simply is not activated; hence, the quality rarely becomes an issue. If the ability to access and analyse the data was better, it is likely that the quality of the data would be a more outspoken issue.

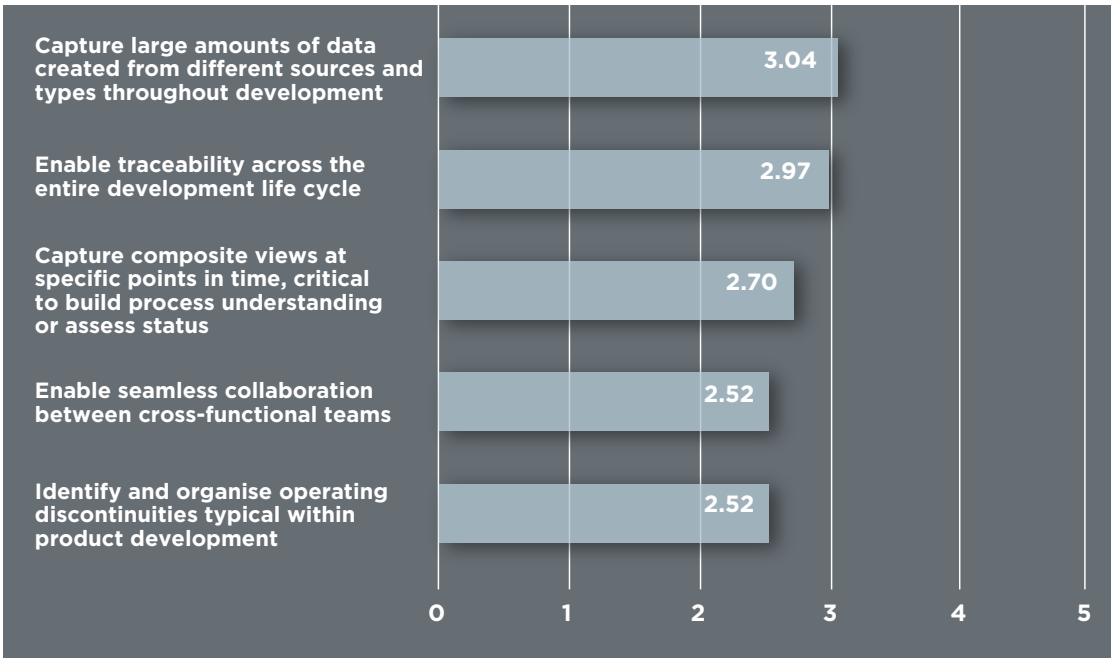
Overall, the current information systems are rated poorly with regard to their data management capability. The statement 'Our data systems are sufficiently designed so that we don't need to spend time looking for information' applies only to a very small degree. However, finding the required information should not be an issue in any drug development organisation. Apart from the fact that the inability to find data puts the life science company at some regulatory risk, time spent searching for information is expensive. It consumes the resources that potentially add business value – and ultimately: If the desired information is lost, new *and expensive experiments may be required to generate new data.

If the pharmaceutical business wants to move from hypothesis-driven analytics into large-scale, discovery-driven analytics, finding data and analysing data across studies should be as simple as retrieving and analysing data within individual studies.

An outdated infrastructure may be characterised by isolated information silos whose inadequate processes and lack of data management resources impede the business. *Figure 9* paints a dismal picture of the current information systems' abilities. A key parameter such as the ability to trace across the development cycle scores very low, and even the ability to capture large amounts of data created from different sources does not score particularly high.

FIGURE 9

On a scale of 1 to 5, where 5 indicates best in class capability, rate your current information systems' ability.



Conclusion and NNIT Recommendations

The increasing amount of data is putting the existing business model under pressure. To survive, companies need to exploit data more deeply. Information Management is recognised as a valuable means to achieve this ability.

Transparency of data is required as it provides control of data and will enable companies to maximise the exploitation of the captured data.

Considering the speedy, technological development, it is important for the pharmaceutical industry to keep up with the pace in order not to become completely detached from the technological opportunities. Adaptation of the new technologies, introduction of new transformative business processes and a strategy for attracting the scarce data scientist talent are necessary.

Information Management may very well be the perfect tool to accomplish priority goals as it supports cross-organisational collection, analysis and reporting of large quantities of complex structured and unstructured data.

Information Management Strategy

- Companies must acknowledge that understanding Information Management is simply the first step on the road towards data-driven decision power. The true challenges lie within the adaptation of Information Management to individual business models. A successful strategic framework supports the implementation of Information Management and ensures that company-wide focus is sustained within the area.

Data Quality

- Apart from the fact that immaculate data quality is crucial for reporting to authorities and for being compliant, it is also highly critical to enhance the data quality as this constitutes the foundation for analysis and decision.

Optimisation of Processes

- Pharmaceutical companies must look at which processes should be optimised in order to ensure standardisation and to ensure that facets in the data value chain support the information management strategy.

Competencies

- Strategic initiatives within Information Management need to be supported by adequate resources. It is time to rethink organisational roles and responsibilities to truly harvest the benefits of Information Management.

Look for the Competitive Advantage

- Competitive advantages lie in the wake of Information Management. Pharmaceutical companies may, by implementing Information Management, place themselves in a situation where organisational data unveils the true power to support business goals.

NNIT 11.2013

NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality. We apply the latest advances in technology to make our clients' software, business processes and communication more effective.

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