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THE ROLE OF SCIENTIFIC BUSINESS SYSTEMS ANALYSTS IN DRIVING SCIENCE FORWARD

Zifo
SCIENTIFIC INFORMATICS

Scientific Informatics BSA

Abstract

Research and development (R&D) Informatics projects are rapidly growing both in number and scope in recent years. While all informatics projects have long relied on business systems analysts (BSAs) for successful project delivery, we have identified that **R&D Informatics projects require specialized BSAs with unique skills, having scientific domain knowledge and understanding of scientific informatics tools and technologies to be successful**. In this paper, we discuss R&D Informatics projects, the role of SI-BSAs and maximizing organizational value through successful SI-BSAs.

Introduction

Research and Development Informatics Projects

The Covid-19 pandemic has highlighted the intricacy of the life sciences research and development sector. This industry is characterized by large growth and rapid innovation, as demonstrated by the 295% increase in pipeline drugs since 2001[1]. While the rate of innovation leads to discoveries and breakthroughs, it must be matched with equal innovation in the scientific informatics so thatscientists have the tools and throughput to sustain their innovation and continue their research.

Ultimately, the goal of R&D Informatics Projects is typically one, two, or all of the following:

- *to enable scientific business efficiency*
- *to create/deliver tools that allow for more rapid and data-driven decision-making*
- *to improve Quality and Compliance*

A successful R&D informatics project involves delivering the highest value to the Scientists. This can only be accomplished if the needs of the Scientists are well understood. Therefore, the role of the SI-BSA becomes crucial to project success. ***A Scientific Informatics Business Systems Analyst (SI-BSA) serves as the conduit between scientific subject matter experts (SMEs) and the IT team. They are responsible for articulating the scientist's needs, priorities, pain points, and gaps through both workshops and documentation. They are also responsible for ensuring that the technical team understands these requirements***.

> Given the unique nature of Scientific Informatics projects : rapid innovation & evolving Science and Technology, the SI-BSAs must possess unique skills to be successful. It is therefore helpful to look at this role in more depth.

Skills of a Scientific Informatics Business Systems Analyst

Primary skills

There are common aspects of business analysis that any business analyst must possess, whether invovled in science informatics or not. The following are some of the major elements that are common across BSAs and SI-BSAs. Business Analysts are unique project roles, in that they represent the business, and all SI-BSA responsibilities should be performed from that perspective. Eventually, once a SI-BSA has enough experience and a relationship with the business, they themselves become an extension of the Business team and can effectively help meet all the business goals for a project.

In addition to gathering the requirements and forming a relationship with the business, SI-BSAs are also responsible for analyzing the needs of the business and communicating their findings to all stakeholders of the project.

Business and Systems Analysis

An essential skillset for BSAs is the ability to perform the vital business and systems analysis for a project with wise reasoning. While each project is different, this often requires the ability to correlate and integrate abstract business needs and high-level requirements into a detailed workflow. In turn, once a workflow has been generated, the SI-BSA then needs to translate them into technical and system design requirements. It is also important that SI-BSAS can summarize complex processes into critical capabilities that can be presented to the project team. Another important skill is the ability to appreciate and resolve differences and inconsistencies in the user, functional, and non-functional requirements. The use of various business analysis tools such as process mapping, data modeling, gap analysis, requirements gathering, journey maps, etc. is essential for the concise presentation of these analyses to diverse scientific, technical, and management audiences.

Communication

Communication is the most important skill in the SI-BSA arsenal and is integral to every other aspect of the role. SI-BSAs need to be able to articulate abstract ideas and concepts effectively and simplify to diverse audiences with a wide array of backgrounds. It is important for a BSA to understand the changes that need to be made when discussing project concepts with an expert versus a novice. In addition to verbal communication, SI-BSAs also need to be effective users of visual tools and written media to summarize the content and present it effectively. This necessarily requires a constantly evolving understanding of the appropriate tools and technologies.
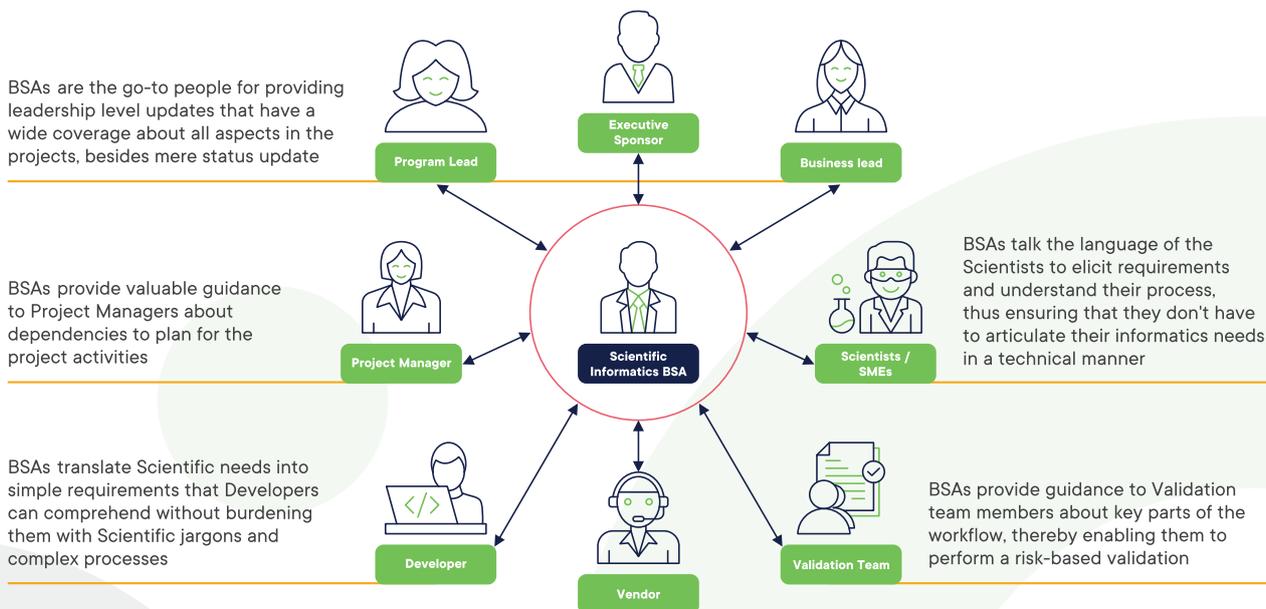
Supporting skills

User Experience

When some projects employ user experience and user interface experts, SI-BSAs must be able to provide guidance on these issues when these teams are unavailable. Particularly since they put themselves into the shoes of the business, SI-BSAs should be able to provide useful feedback about how scientists will interact with a system and what interfaces and designs will best suit their needs. They also need to be proficient in collecting the feedback from the scientists and be able to present it to the project team in an effective way. It is important to unify the user experience across systems and workflows, in which SI-BSAs should be involved with at every step because of their extensive knowledge of the business and science.

Systems Architecture

Systems architecture skills are important for SI-BSAS since they provide an outlet for describing business needs and presenting solutions. As SI-BSAs are often required to generate visuals as part of their role, wireframing and sequence diagrams when discussing project solutions with the project team. Additionally, understanding how to interpret, and even build these diagrams is key to understanding the chosen solution and communicating it to the business when necessary. Also, an understanding of reference architecture, entity relationship diagrams, and concept maps is very benficial for any SI-BSA.

Project Management

While most, if not all, informatics projects have a dedicated PM, the SI-BSA often has many hidden project management responsibilities so skills in this area are important. Certainly, the SI-BSA is a critical player in terms of planning a project as well as in scoping and framing due to their interactions with the business. In fact, scope management often becomes a SI-BSA responsibility since they must escalate any early indicators to scope creep that could delay the overall project. *SI-BSAs are well-suited to identify these instances of scope creep as they best understand the stakeholder acceptance criteria and are often aware if not part of the original scope definition*. SI-BSAs must also be aware of business timelines and ensure that pressures on these timelines do not lead to false approvals from the business. While a lack of comments on a project can often be considered an approval, BSAs must challenge future users to stay involved during a project and assist them in managing the project milestones and timelines.

BSAs are the go-to people for providing leadership level updates that have a wide coverage about all aspects in the projects, besides mere status update

BSAs provide valuable guidance to Project Managers about dependencies to plan for the project activities

BSAs translate Scientific needs into simple requirements that Developers can comprehend without burdening them with Scientific jargons and complex processes

BSAs talk the language of the Scientists to elicit requirements and understand their process, thus ensuring that they don't have to articulate their informatics needs in a technical manner

BSAs provide guidance to Validation team members about key parts of the workflow, thereby enabling them to perform a risk-based validation

Program Lead | Executive Sponsor | Business lead | Project Manager | Scientific Informatics BSA | Scientists / SMEs | Developer | Vendor | Validation Team

Unique skills of the Scientific Informatic Business Systems Analyst (SI-BSA)

With Science evolving rapidly, new modalities such as ADCs, and mABs, new scientific technologies such as NGS, RNAi are all making data continually more complex. New laboratory techniques and instruments provide opportunities for automation and efficiency. All of this change demands more informatics solutions and new projects. This presents SI-BSAS involved in these projects with a unique set of challenges and opportunities which means they must possess special skills to be successful. As such, SI-BSAS are often part of a project from conceptualization to strategy implementation. During this entire project phase, SI-BSAs must continue to have productive conversations and requirements-gathering sessions with scientists while providing the voice of the customer guidance to the project team. Below, we have identified several major categories of skills that are specifically important as an SI-BSA over a typical BSA.

Science

The most important skill of an SI-SBA is the ability to observe scientific processes and identify opportunities to improve operational efficiency in the lab/manufacturing plant. *A strong and deep understanding of the underlying scientific domain is fundamental for SI-BSAs to be successful. In addition, they also require an understanding of the software, instrument technology, mathematics, and data constructs for the given scientific field*. Understanding the scientific language of the business is essential, as the SI-BSA needs to have productive conversations with the business for the project to move forward. Another key skill is the ability to shadow scientists in the laboratory environment and ask relevant and directed questions that improve understanding of the scientific process, pain points, and

needs. This is a customary practice followed by SI-BSAs used to understand and map scientific workflows. Finally, an understanding of the lab organization and operations is necessary to define workflows appropriately. Some of this knowledge can be gained by shadowing scientists in the laboratory environment, but SI-BSAs should be able to self-answer questions of throughput, cost, quality, etc. without always consulting the business.

Technology

It is important for the SI-BSA to have a working understanding of the laboratory systems. It is important that the SI-BSA know and understand the various solutions that support research as well as how those solutions can be applied in different project spaces. They should also be able to pick up new technology skills easily and adapt to changes in existing systems.

Data

One of the foundational pillars of R&D organizations is the concept of FAIR data. *With digital transformation and convergence initiatives becoming a top priority for many R&D organizations, the ability to perceive business processes from a data lens is a critical expectation of the SI-BSA*. While FAIR data is a relatively new concept in the scientific data world, other industries have made significant advancements in frameworks and tools that can be leveraged by the scientific community. An SI-BSA will be capable of having their foot in the door of both communities and applying the appropriate tools in the R&D domain.

Regulatory Compliance

As stated previously, R&D Informatics projects often have regulatory and compliance components that add additional layers of complexity. These requirements include good practice (GxP) guidelines for laboratory (GLP), manufacturing (GMP), clinical (GCP), and other interactions. SI-BSAS should be familiar with these various FDA/Regional guidelines and be able to quickly understand and adapt to new releases of these guidelines. This allows SI-BSAs to assist the project team with a risk-based approach to R&D Informatics projects.

The Good-to-Great Differentiator

From a SI-BSA's perspective, to succeed in the role, one must have empathy and be able to gather and analyze requirements, design solutions, and articulate value all from the perspective of the scientific business. Successful SI-BSAs will be in touch with the industry and up to date on current trends and developments to best assist their customers. Anyone hoping to be involved as an SI-BSA should also acquire proficiency in a range of scientific and technological functions either through the completion of courses through their degree program or through training programs. Many SI-BSAS come from a laboratory background and have direct exposure to laboratory activities through their experience, which can be of great benefit for the role. It is also important to have a working knowledge of the ethos that drives drug research and development activities:

- Curiosity
- Empathy and Emotional intelligence
- Question Framing
- Ability to work in both abstract and in detail at the same time
- Dynamic planning and execution
- "Get it done" attitude
- Learning Agility
- Ability to increase capability and bandwidth in short notice
- Grow & leverage knowledge capital (Templates, Methodologies, Toolkits)
- Creating and nurturing connections with Industry Leaders
- Manage a global delivery team
- Ability to convince stakeholders
- Ability to manage Conflicting interests

In short, SI-BSAs need all aspects of empathy, learning agility, scientific focus, emotional intelligence and technology acumen. Lab experience gives an added advantage of credibility with other scientists

Maximizing Organizational value of SI-BSAs

To take advantage and maximize the value of an SI-BSA, it is important as organisational leaders to understand the career trajectory that an SI-BSA might have. Designing a competency framework for SI-BSAs will add great value to the organization.

The overall career progression of a SI-BSA begins with contributing to strategic informatics initiatives, progressing to leading informatics projects and building informatics strategies & roadmaps. Often, this leads to industry wide recognition where the SI-BSA serves as a thought leader - a strategic consultant if you like. They grow and perhaps head business relationships at scientific organizations, managing liaisons between business and IT, or even executive-level leadership for informatics strategy divisions.

To maximize the role effectiveness, it is essential for leaders to select SI-BSAS and invest in training sessions that will set them up to succeed

- Identify the minimum qualification such as a few years of industry experience as a scientist/researcher, with science degree qualifications.
- Plan for specific regular deep science topics to impart relevant knowledge
- Specific training in the visualization of concepts and fuzzy processes

- Make SI-BSAs knowledgeable about industry frameworks for data management, automation, digital transformation, and train them on how to apply them for creating new project ideas and scoping them.
- Train them on specific Change Management concepts, creating change network diagrams linking features to benefits.
- Enhancing Scientific informatics product knowledge through hands-on experience and product-specific training.
- Supplemental concrete experience on projects with allotted time for reflection.
- Create SI-BSA special interest groups (SIGs) in various knowledge domains for better knowledge exchange and mutual support.

As SI-BSAs progress through their career, delivering strategic impact through their knowledge becomes apparent. Investing in strategic concepts allows for successful SI-BSAs career progression and maximizing strategic impact.

- Training in value chain analysis and business alignment topics, including framing of department-level KPIs/metrics.
- Involve well-trained SI-BSAs in creating IT and Data strategies – their knowledge will come of tremendous use.
- Encourage SI-BSAs to perform the role of Innovation champions, leading workshops to create new concepts and ideas.
- Organizations must invest in mechanisms to retain the knowledge created as part of these analyses, in the form of robust living documentation, recordings, and artifacts.

Conclusion

Successful consulting engagements are not achieved by deliverables and recommendations alone. **Success is defined by the customer's adoption of recommendations and their application value to their scientific teams. Successful engagements require SI-BSAs to not olny aid customers understanding of the analysis findings, but also to support and enable the the organization to agree on a strategy and commit to the implementation of that strategy**. The SI-BSA is key to this because they understand the perspective of the scientists and can successfully translate their needs to project teams due to their broad understanding of both the scientific domain and informatics projects. In many ways, SI-BSAs are teachers and coaches, helping IT teams understand science so that they have the perspective of a scientist as well as teaching and coaching scientists about technology aspects so they can better understand their workflows and system design. So, SI-BSAs are key players in scientific informatics projects and are critical to their delivery and success.

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About the Authors

Aishwarya Balajee

*Head of Digital Solutions, North America
Passionate about accelerating Science. Helping
customers define and implement a Digital Strategy
Expertise - Strategic consulting across the
R&D spectrum*

Sujeegar Jeevanandam

*R&D Subject Matter Expert & Scientific Informatics
Architect with more than 15 years of experience across
the R&D continuum in Life Sciences, Material Science,
FMCG & other industries*