Paper LI03

Janssen's Journey Towards a Culture of Innovation

Sumesh Kalappurakal, Janssen R&D, NJ, US
Sangeeta Bhattacharya, Janssen R&D, NJ, US
Marion Wolfs, Janssen R&D, Breda, NL
Lisa Lyons, Janssen R&D, NJ, US

ABSTRACT

The development of best-in-industry data science capabilities is critical to Janssen's ambition to be the best innovative healthcare company. We are working to integrate data sciences and other innovative approaches in every aspect of Janssen Research & Development culture. This presentation will discuss various innovative methodologies that we are exploring in our Integrated Data Analytics & Reporting group such as machine learning, natural language processing, robotic process automation, etc. We will also discuss how we are adopting design thinking methodology to build an innovative and high-performance cloud-based statistical computing environment. We will share our journey towards a culture of innovation.

INTRODUCTION

With an engaged global team of dedicated employees, it is Janssen Integrated Data Analytics and Reporting group's (IDAR's) mission to bring expert capabilities to enable the collection and conversion of data into knowledge in order to support the best possible data-driven decisions as early and effectively as possible. IDAR aspires to become the most efficient data analytics and reporting organization in the world, supporting the delivery of innovations end-to-end, starting from study planning and data collection to data analysis and reporting, and finally submitting high-quality, compliant applications for regulatory approvals to improve and extend the lives of millions; with the best people, culture and processes. Our IDAR group comprises of the following sub-functions, where we are pushing innovation to gain efficiencies in what we do in order to bring much needed medicine faster to our patients:

- Data Management and Standards
- Risk Management and Central Monitoring
- Statistical Programming and Analysis
- Regulatory Medical Writing
- Data Transparency

In addition, we are also collaborating with our broader Janssen data Sciences teams on many TA specific projects.

We realize that pushing an organization out of their comfort zone can be looked upon as disruption, but we have implemented a robust change management process, by embracing techniques like design thinking. With the support of senior management, leaders within the organization are empowered to challenge the status quo, encourage innovation and expand data sciences.

INNOVATIVE APPROACHES

1. Data Collection

Clinical trials are moving into an era of continuous electronic data collection utilizing devices and techniques, such as wearable sensors, mobile phones, electronic journals and digital imaging. This has a disruptive impact on the way we monitor our clinical trials and opens opportunities to better manage risks associated with the conduct of clinical trials. However, new technologies may also create unanticipated risks that require novel solutions. As leaders it is important

to provide a strategic vision to our teams and help create a culture of change, embrace diversity and help connect the dots to prepare our teams for this digital transformation to get the best outcomes from our teams and our patients.

Within IDAR we are leading our teams to drive value and scalability through standardization, innovation and technology. Our vision is to master the art of translating science into real time consumable data assets, accelerating healthcare business decisions contributing to a world without disease. Standardization, innovation and adoption of new technology is highly dependent on the close collaboration within and between functions, leveraging expertise and skills beyond boundaries and even between organizations. The examples below are a sampling of how our R&D organization is going beyond boundaries to future innovation, automation and a culture of change.

1.1. Clinical Data Standards

Within our Clinical Data Standards group we have established the concept of Data Life Cycle plans at the therapeutic and disease area levels that include end-to-end standards from collection to analysis. These standards also aid in efficiencies downstream including the set-up of our targeted source data verification (tSDV) and Study Specific Reporting (SSR) visualizations for risk-based safety monitoring We are developing therapeutic and disease area subject matter experts to drive the creation and adoption of standards. We actively monitor standards usage across therapeutic areas and have seen significant increases in the adoption of standards helping to drive efficiencies and scalability. Additionally, we are maximizing the value of standards and data curation by investing in a Medidata Repository platform that will enable an end-to-end metadata driven flow from eCRF builds to submission-ready SDTM.

1.2. Continuous Electronic Data Collection

Continuous electronic collecting of data enables us to monitor the data real-time, on an ongoing basis to identify systemic issues and it facilitates early decision making. Electronic data collection eliminates the risk of transcription errors do to manual transcription of data in the EDC as well as minimize the need for source data verification of this type of data.

Currently Johnson & Johnson is collaborating with Apple, Inc. on a multi-year research study conducted in the United States that aims to analyze the impact of Apple Watch on early detection and diagnosis of atrial fibrillation and potential to improve outcomes. The study goals include;

- Measuring the outcomes of a heart health engagement program with irregular rhythm notifications on Apple Watch.
- Assessing the impact of a medication adherence program using an app from Johnson & Johnson.

Janssen along with other pharmaceutical companies are collaborating on an EHR2EDC pilot evaluation study in which six clinical trials have been selected (4 oncology and 2 cardiovascular). The pilot evaluation study is called “TransFAIR” for Findable, Accessible, Interoperable, Reusable data. It is the first international multi-centric study aiming at demonstrating the ability to use EHRs data as eSource to pre-fill sponsor eCRFs. The first data domains mapped by the project are: demographics, vital signs, laboratory and medication. The EHR2EDC model has been installed at hospital sites and user acceptance and usability testing is ongoing as of August 2019. The module will facilitate eCRF pre-filling with data from the EHR and other hospital information. Upon investigator approval, the extracted data can be submitted directly into sponsors EDC system. TransFAIR as a mirror to each clinical trial.

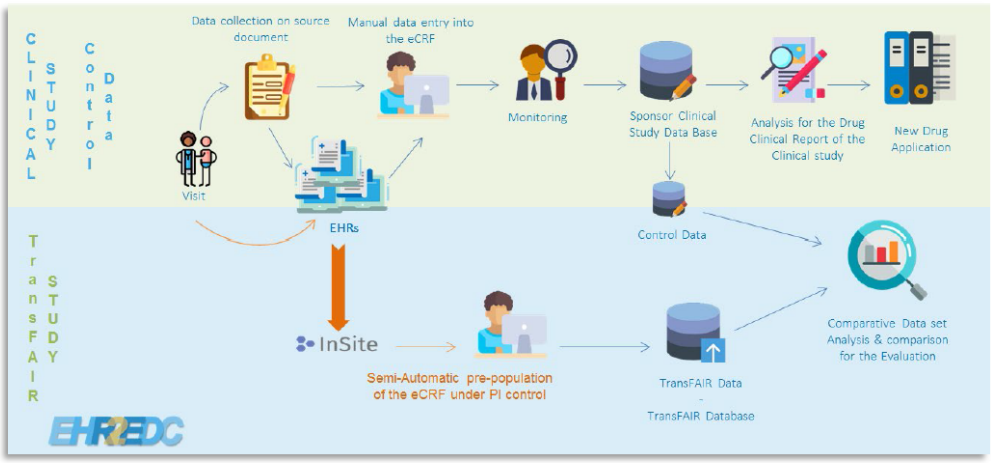


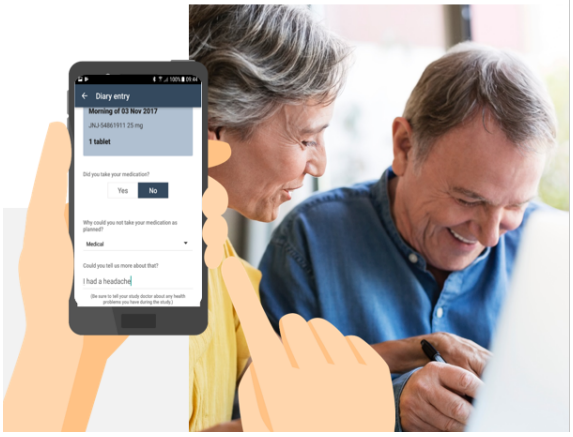
Figure 1: TransFAIR is setup as a mirror to each clinical trial

Source: EHR2EDC From Electronic Health Records to Electronic Data Capture Systems Highlights – Newsletter #3 – July 2019

Another key initiative is the Integrated Smart Trial Engagement Program (iSTEP) this program is in pilot phase and involves close collaboration between functions to provide more efficient medication tracking and real-time data collection and monitoring through patient app's.

The program has three main features:

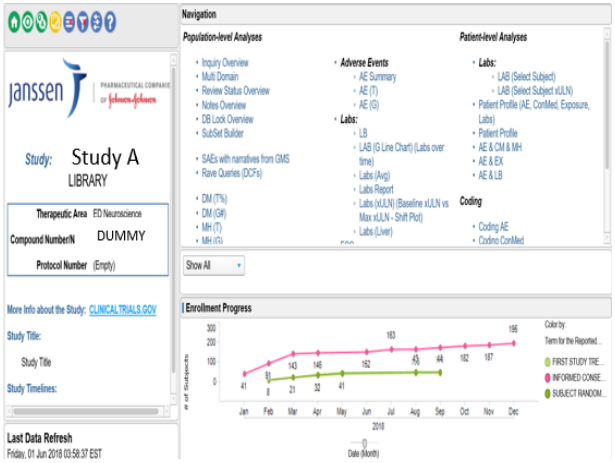
- Site Kit Tracking – ensuring the "right kit to the right patient"
- Smart Blister - ensuring the "right pill to the right patient"
- Patient App – real-time data collection through:
- Learn modules
- Medication intake diaries
- Questionnaire diaries
- Subject surveys
- Personalized notifications
- Motivational messages



1.3. Data Ingestion, Transformation and Submission

Another focus area includes a new data transfer agreement process, adding simplification and consistency for standardizing and automating third party data to achieve **real time consumable** data assets.

Maximizing the value of therapeutic and disease area standards by implementing a Medidata Repository will enable efficient set-up of an automated data flow. The strategic roadmap includes early availability of source data and high refresh rates along with data conversions from source to internal data review model (DRM) and submission ready SDTM with pre-post checking to monitor the process. Implementing visualizations to consume the internal data review model for real-time decision making for dose escalation studies in Early Development as well as enable risk-based safety monitoring or prediction of endpoints to monitor errors related to primary end point collection through SSRs. This ongoing evaluation will allow patient safety and efficacy monitoring to be enhanced and corrective actions taken to increase the trial's chance of success.



Fostering the culture of change, out of box thinking our Innovation Lead, whose responsibility to bring more automation and efficiency to the group initiated a proof of concept project the automation of quality checks performed on submission package before posting to regulatory authorities. This project has now transitioned to a fully funded robotic processing automation (RPA) project, further permitting greater efficiencies from a quality, time and cost perspective.

2. Data-driven Risk Management

With a strong push from the health authorities, the pharmaceutical industry is moving towards a more risk-based approach to the way we monitor our clinical trials. The Janssen RBM model is based on the ISO3001 Risk Management framework and is exploring the use of NLP, predictive modeling and machine learning to enhance our risk assessment process, enable the prediction of risks and analyze risk interdependencies. We are using NLP to categorize protocol deviation and escalated issue information in monitoring visit reports, improving the capability to analyze risk.

3. Statistical Programming and Analysis

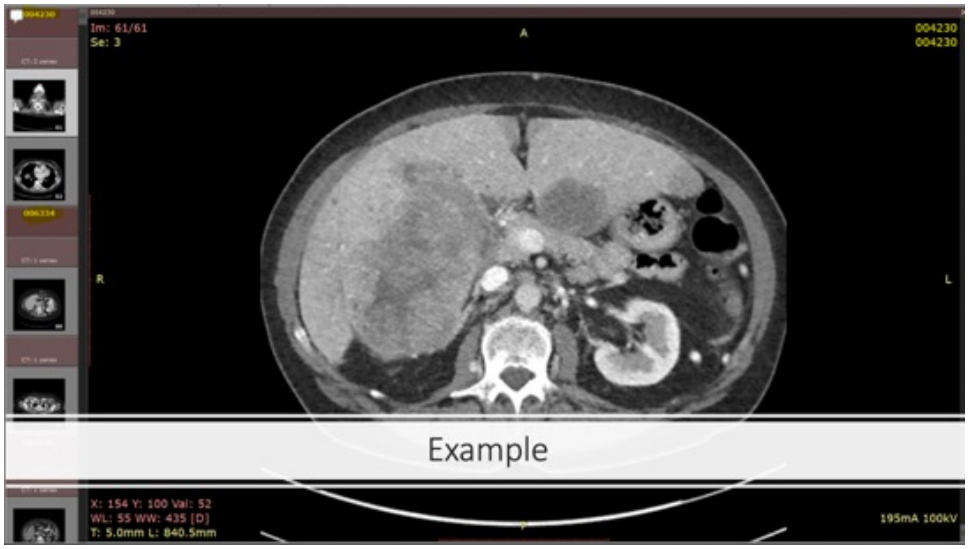
In statistical programming and analysis, our mission is to provide analytical programming solutions that enable early and effective data-driven decisions to bring novel therapies to market as quickly and efficiently as possible. As a data analyst, we provide one of the most needed services in business today, triggering important decisions with the insights from the clinical data., and finally reporting and submitting the data to agencies as part of new drug applications. In order to reduce the time that much-needed medications reach our patients and gain efficiencies, we are looking into many automation strategies (eg, TFL's generation from SAP). We also provide much needed data wrangling and curation support so that our TA data scientists can consume that data and can use predictive & prescriptive modelling to identify novel target biomarkers. We are also utilizing Real World evidence data as part of our submission strategy, and as statistical programmers have a critical part to play in ensuring, this data is submitted to FDA, in the expected format.

We have a department wide effort to move our default programming language from SAS to R, which would enable us to be nimble in creating new analysis in interactive manner, for decision making. We are also investing in creation of a cloud-based metadata driven statistical programming environment with high performance compute platform that includes SAS Grid and R as statistical engines coupled to custom workflow. This system will be hosted in our own VPCx Amazon Web Services (AWS) instance using some innovative microservices from AWS. This a one of the kindly of innovative GxP system built in JNJ to meet our needs.

We envision that in the near future, data analysts will be equipped to present advanced analytics such as predictive and prescriptive models, including creating decision trees, running tests and logistic regressions, and performing market basket analysis.

Hidden within CT and MRI scans is a wealth of metadata that requires de-identification of patients in order for it to be shared and used to advance cancer research while protecting patient privacy. Without the technology to anonymize these data and governance to guide the process, critical information would be unusable in the search for cancer cures.

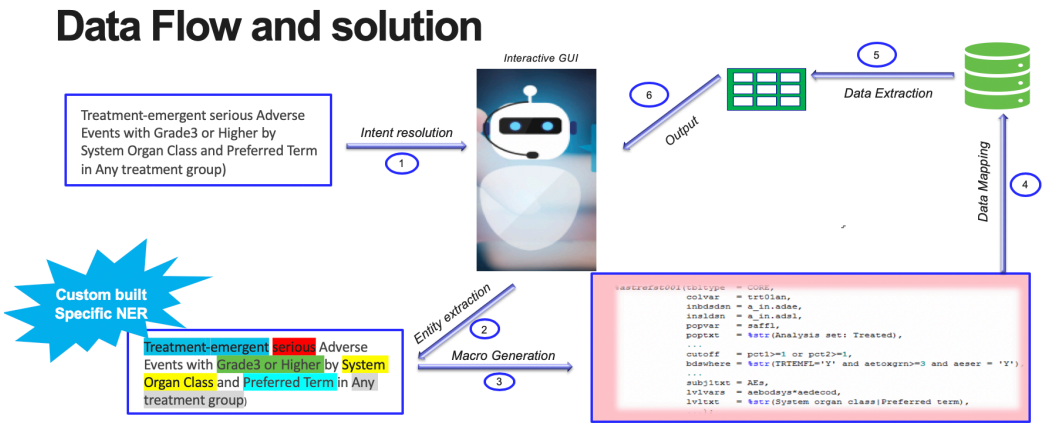
The IDAR Data Transparency Team and Analytics Innovation Team within Statistical Programming collaborated to anonymize over 65,000 CT scans from the phase III study. The data, which were in the international DICOM (Digital Imaging and Communications in Medicine) standard with roughly 500 attributes per image, would have had to be manually reviewed, anonymized and validated.



Fortunately, the Analytics Innovation Team was able to create a package using open source information from the Python platform that facilitates the review and anonymization in accordance with the patient mappings in the clinical study database. This was a great example to showcase some of our innovative capability by stretching out to do analysis outside of our comfort zone.

As the volume of clinical data continue to increase at a staggering rate, Artificial Intelligences (AI) and Machine Learning (ML) methodologies are poised to be the engine to drive innovation. In programming we also see opportunities to adopt these methodologies to increase automation. We are prototyping a concept of using a virtual assistant to automate analysis report generation.

A new paradigm from a repetitive and cumbersome manual process to applying cognitive automation leveraging a Neural Networks/ ML algorithm which interpret human requests and performs key actions.



ENVISIONED DATA PROCESS

Reduce daily cumbersome manual work for statistical programmers with high quality and consistent auto reports generation and search process, keep user focused on high-level thinking and decision making

4. Regulatory Medical Writing

Regulatory Medical Writing is focusing on automation of repetitive tasks and processes to help our writers focus on delivering key insights on our medicines while relieving them of routine activities. Examples of process automations are two of our collaborations with the Statistical Programming and Analysis group where study participation, exposure and other key information is presented in a tabular format as part of the patient narrative. More recently the Innovations Team within Programming prepared a web-based Data Visualization Tool to facilitate analysis of TLGs for a wide variety of documents for the writing group. The writing group has also partnered with IT to automate the review and tracking of patient narratives using SharePoint workflows and Office365 add-ins.

CONCLUSION

Although not all people are born with innovation in their DNA, everyone can learn to be innovative. Innovations are new dots that potentially change everything, dots other's missed, dots that are ignored. As an effective leader, we should recognize the importance of embracing diversity and know how to connect the dots amongst those differences to get the best outcomes from our teams. As leaders, our remit is to recognize great ideas, form a vision around them, motivate our teams and communicate.

While raising the bar and expectations for raising our operational voices, increasing our functional and technical capabilities and simply allowing for more prudent risk taking. Leadership is supporting external visibility and involvement in industry work groups and forums. Growth and leadership opportunities at all levels in every function are helping our teams through their individual culture of change transition – through better understanding, more ownership and alignment.

We as leaders, need to be revitalized in a manner that inspires hope and evolution in order to propel innovative opportunities for growth, prosperity and sustainability.

"Innovation is the difference between a leader and a follower." - Steve Jobs

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CONTACT INFORMATION

Sumesh Kalappurakal
Janssen R&D
New Jersey, USA
Email: SKalappu@its.jnj.com

Sangeeta Bhattacharya
Janssen R&D
New Jersey, USA
Email: sbhatt11@its.jnj.com

Marion Wolfs
Janssen R&D
Breda, NL
Email: mwolfs1@its.jnj.com

Lisa Lyons
Janssen R&D
New Jersey, USA
Email: llyons3@its.jnj.com