AI and the Cloud: Changing the Clinical Trial Experience

It doesn't take a crystal ball to see that there are a number of exciting life-science industry trends that will profoundly influence clinical trial solutions in the years to come. Chief among them are:

- Patient engagement and patient centricity will be king, driving digital transformation with IoT and AI.
- Robotic Process Automation (RPA) will change the way we work.
- Life-sciences/healthcare industry will master AI and Machine Learning.
- CROs will expand beyond clinical operations to more "IT-like" solution offerings to continue to add value to the entire drug development chain.
- Pharma will start POCs to use blockchain for data sharing.
- AI will drive new user experiences, an important aspect of how we interface with data.
- Pharma will embrace the cloud, more than ever before, with validated solutions that serve specific purposes.

But haphazard fortune telling has no place when it comes to the future of clinical trial services and drug development. As renowned management consultant Peter Drucker said, "The best way to predict the future is to create it."

The data analytics industry has taken those words to heart, in particular regarding the last two trends: AI driving new user experiences with data, and pharma embracing the cloud more than ever before with validated solutions.

AI Driving New User Experiences with Data

Natural Language Understanding (NLU) is opening doors in the life-science industry that, until recently, were bolted shut. The application of AI to NLU engines is creating a revolutionary paradigm shift for drug development, catapulting the traditional user experience (UX) on an impersonalized dashboard to a conversational experience (CX) involving personalized analytics. This paradigm shift is transforming the conduct, speed and outcomes of clinical trials.

UX > CX

Impersonal Dashboard
to
Personalized Analytics

As we head toward the third decade of the 21st century, clinical operations will begin to revolve around customized NLU engines that facilitate understanding, interpretation and conversation within the clinical operations enterprise. The life-sciences industry still has a text challenge: how to get structured data, and ultimately valuable insights that inform business objectives, from unstructured text. In other words, how to interpret meaning from the vast quantities of unstructured text that exists, once that data is centrally aggregated.

Computers are usually really good at understanding binary language but have traditionally fallen short at human, or natural language, understanding. AI-enabled personal assistants like Siri, Alexa, and Google have been interpreting and answering consumers' questions for years. These chatbots combine search, voice recognition, and Natural Language Processing (NLP) to provide consumers with a basic conversational experience. However, we can't throw Alexa at a pharma problem because it's not contextualized for pharma; it's not domain-centric. The questions Alexa is trained for are much more generic. We have to think about how we leverage domain-centric AI to provide higher producing yields for pharma and biotech. Until recently, widespread use of similar technology in the complex, data-intensive world of drug development lagged behind.

Unique new NLU engines can now perform tasks or services for an individual using text, voice, and other methods of interaction. Such NLU engines leverage NLP and entity expression matching, as well as search and voice recognition to provide a very sophisticated conversational experience that facilitates intent — the posing of specific questions regarding the data at hand — to inform options and to set a recommended course of action.

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NLU engines facilitate a customized conversational experience within the clinical operations enterprise, allowing the user to find information they care about, based on their role in an organization and the information needs they have at that particular point in time. It enables them to move beyond the traditional dashboard that has been generally prescribed for their organization. Clinical researchers can now ask questions of their data, pin their own FAQs, and look at recommended questions that colleagues with a similar profile have asked about the enterprise at hand.

For instance, if I want to explore subject enrollment variances for a particular study at any given point in time, in a matter of seconds I can query my raw data verbally using an NLU engine and receive the answer, not only verbally and textually, but also visually, with charts, graphs, infographics.

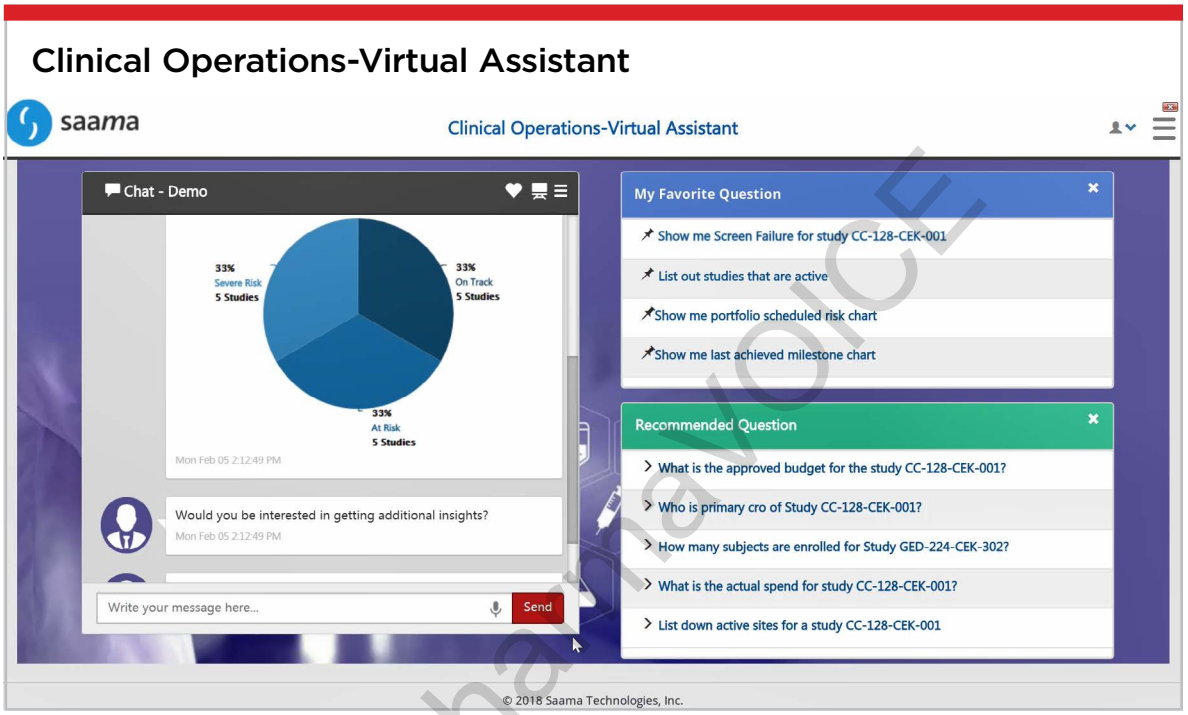
Pharma Will Embrace the Cloud with Validated Solutions

The other life-sciences industry trend that will have a major impact on clinical trials is the use of validated cloud solutions. Pharmaceutical and biotechnology companies now have access to cutting-edge, AI-informed, cloud-based analytics solutions designed to optimize clinical development processes and deliver outcomes by streamlining the steps of the entire clinical data journey. Such cloud-based solutions can unify previously disparate data

sources produced by a multi-vendor business model and traditionally housed in multiple silos across an organization. These platforms provide an integrated experience for clinical development, arriving at a time when, more than ever before, pharmaceutical companies are struggling with increases in drug development cycle times and cost overruns, and pressure is mounting for better command of the data that runs their business to make drug development processes more efficient.

Such validated cloud-based solutions integrate multiple sources of structured and unstructured data, containing pre-built capabilities for data ingestion, integration, and analysis, which can be leveraged to generate real-time business insights within weeks. Pharma and biotech benefit from faster time-to-market, reduced costs, and better patient and business outcomes. Specific advantages include:

- Data lifecycle management solutions that specialize in integrating and harmonizing data from disparate sources to create a clinical data lake where all the data resides, prepped and ready for analytics, allowing a clinical research team to assess risks across all studies and to evaluate performance based on key metrics.
- Clinical trial feasibility solutions that optimize the processes governing enrollment, investigator identification, site selection, and patient burden, using Real World Data (RWD) to identify eligible patient populations and principal investigators and evaluating and quantifying the likelihood of successful patient enrollment and site selection.
- Cohort generation solutions that identify patient populations based on inclusion-exclusion criteria, organizing real-world patient information based on diagnosis, drug therapy, and procedures, to pinpoint population groups that fit specified criteria.
- Commercialization analysis solutions that provide the therapeutic value of clinical products, within a market basket and across geographic areas, allowing companies to predict the reception of a drug or treatment in the market on the basis of claims/EMR data and mapping it across similar products, market trends, and competitor activity.
- Patient journey tracking solutions that facilitate the evaluation of treatments, disease progression, outcomes, and total economic costs to provide decision-making insight into how a given disease is treated and/or managed.



Cloud-based solutions will produce game-changing results, allowing trial teams to focus on research and analysis versus data wrangling, and significantly opening up new possibilities for how to manage data in the life-sciences industry.

Impact of Future Trends

This AI-driven paradigm shift of leveraging domain-centric NLU engines positively impacts and transforms two key areas of clinical trial operations:

- Better patient matching for clinical trials — only 3% of the patient population participates in clinical trials. This is due to poor access to eligible patients' profiles. Using NLU engines, pharma can partner with care providers and mine de-identified physician notes and map to complex inclusion and exclusion criteria. AI is aiding in accelerating this process with higher fidelity and bring well-needed clinical trial as a care option for patients.
- A transition from UX to CX (user experience to conversational experience) — conversational experience with customized NLU engines in the life-sciences industry facilitates:
  - **Interaction:** Initiates a conversation over multiple natural channels of engagement.
  - **Engagement**: Builds a natural response/dialogue and continues the interaction.
  - **Interpretation:** Identifies intent and extracts entities/relevant information using AI.
  - **Integration:** Generates a response from the knowledge base and system APIs.

By embracing validated, cloud-based solutions for clinical trials, pharma and biotech can achieve significant efficiencies in site identification timelines and reduction in non-enrolling site costs. Furthermore, the flexibility of cloud-based platforms, in terms of algorithms, speeds up time-to-market by almost five times, compared to standard platforms.

The bottom-line: AI and cloud-based technology will offer unprecedented insights for clinical drug development operations, shaving both years and costs off the launch of new drugs for the patients who need them. PV

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