Exploring Use Cases For Tokenizing Clinical Trials

By Melissa McDonald, Director of Operations, eClinical Development and Delivery, Clinical Trial Tokenization, ICON plc

In drug development, Pharmaceutical and Biotechnology organizations are leaning into data-driven insights to aid decision-making and lower the burden on physicians and patients to conduct and participate in clinical research. The paradigm has shifted even more since the global pandemic to adopt more decentralized methods of data generation versus traditional clinical study methods. Traditional clinical studies can be costly, time consuming and burdensome on patients and sites. As a result, researchers are looking for new and innovative solutions to answer challenging research questions.

One of these solutions is Clinical Trial Tokenization. The adoption of using real world data (RWD) and enhanced insights through analytics and artificial intelligence (AI) is rapidly increasing and in the United States (US), the 21st Century Cures Act encourages use of RWD or medical data in generating evidence or Real World Evidence (RWE) in regulatory submissions. Tokenization is the production of a unique encrypted token, or de-identifier in the place of Personal Identifiable Information (PII). It is already used in many industries, such as real estate, commercial analytics, finance and banking to gain insight into consumer behaviors. When employed in the life sciences, tokenization can be used for clinical research and development to enhance evidence generation.

Streamlined And Efficient Approach To Generating Evidence

Clinical trials already play a crucial role in advancing drug development by evaluating the safety and efficacy of new treatments. However, one aspect that often presents a challenge is the generation of longitudinal data showing what occurs for participating patients before, during and after the clinical study concludes. By harnessing the power of tokenization, drug developers can adopt a secure and efficient method to evaluate the long-term safety and effectiveness of treatments. Clinical trial tokenization is revolutionizing long-term participant monitoring even when patients move, change care practices, have study fatigue or discontinue study participation.

By tokenizing participant PII for consented patients, and matching to a unique identifier, researchers can link to patient records in a privacy-protected manner. These records may include medical claims data, electronic health records, laboratory data, treatment and follow-up records. Tokenization ensures that data remains accessible for long-term analysis. There could be a possibility to eliminate some of the cumbersome paper-based systems, and/or reduce the number of study site visits. By aggregating tokenized patient data within a proven privacy protected framework, researchers achieve a streamlined and efficient approach to generating enhanced clinical evidence. This approach can be particularly helpful where the research requirements include regulatory-mandated long-term follow-up portion of up to 15 years for treatments such as gene and cellular therapy products.

Tracking Effectiveness And Safety Of Treatment In Long-Term Follow-Up Studies

Long-term follow-up in clinical trials is essential for tracking the effectiveness and safety of treatments over an extended period. Tokenization enables the creation of unique tokens for each participant, which can be used to track and monitor their health outcomes in a decentralized manner. Researchers can efficiently collect and analyze long-term data, identifying any potential trends in adverse events, disease progression or concomitant drugs administered. When longitudinal real world data is accessible, visibility of events that may have gone unnoticed during the trial phase, or happened long after the study concluded, can be analyzed. For example, tokenized data can capture an adverse event (AE) occurring in the study population years after the investigational drug is approved and on the market. In addition, researchers can evaluate the patient population taking the investigational treatment through the RWD capture and compare this to the general population not taking the drug.

Enhancing Evidence Generation With Clinical Registries

Traditional registry and natural history studies, whether publicly or privately funded, support the development of improved treatments for patients. These often-lengthy studies are a key initiative for collection and storage of real world information pertaining to a specific disease. A potential benefit for inclusion of tokenization in registries is the provision of de-identified trends and additional enhanced evidence that may answer research questions in a specific patient population. Through tokenized data, researchers can compare patients with a given diagnosis or patient profile to the general population by looking at concomitant medicines, AEs, procedures, and diagnoses codes. RWD may lend insight into diagnosis patterns, pre-existing conditions or risk factors. This secondary evidence generated can lead to more treatments and understandings surrounding a specific condition. Through analytics and reporting over the larger patient population, we can further extrapolate insights that occur in a specific gender or age (i.e., .025% of the pediatric female population has a comorbidity of type 1 diabetes).

Supporting Regulatory Discussions On Post-Marketing Commitments

Regulatory agencies (e.g., FDA, EMA) will sometimes request or mandate a post approval surveillance study (PASS) or require additional safety and efficacy studies for an approved product. Although many factors are captured in the drug approval process, there may be additional evidence gleaned about real world treatment patterns after the clinical controlled environment has ceased. There is a benefit in evaluating the safety and effectiveness of treatments on patients taking approved drugs. Tokenized data can further enhance evidence and generate support for safety and efficacy. This is particularly important in cases of pediatric or vulnerable patient populations. Sponsors may use RWE to support discussions with regulators, as this data supports and can increase significantly the sheer volume of data to be considered.

Tokenization enables the creation of unique tokens for each participant, which can be used to track and monitor their health outcomes in a decentralized manner.

Balancing The Risks And Benefits

Sponsors conducting any type of study, including long-term follow-up studies, must also delicately balance risks and benefits when using new innovative technologies in clinical trials.

Some risks to be considered and managed include:
- Ensuring appropriate patient consent, privacy and data security
- Increased financial costs to implement novel technologies
- Inadvertently unblinding a clinical trial
- Lack of adherence to Good Clinical Practice (GCP

However, the potential benefits of deploying clinical trial tokenization are far reaching:
- Capability to leverage insights for product development, positioning and performance
- The ability to support launch strategies with deeper understanding of product value
- Supplementary data for regulatory discussions/ submissions
- Increased insight and ability to assess diversity, equity and inclusion (DEI) goals in clinical trials

Summary

Clinical trial tokenization has the potential to revolutionize long-term study participant follow-up in medical research. By leveraging the power of this technology, tokenization offers streamlined data management, enhanced privacy and security, efficient tracking of long-term outcomes, lessens the burden to sites and patients and facilitates collaboration among researchers.

When considering including Clinical Trial Tokenization to research efforts, it is important to collaborate with a trusted partner who understands the rigor of research and development within the framework of GCP and regulatory parameters. It takes more than a token to lead to meaningful evidence generation. Deploying Clinical Trial Tokenization requires an expert in consent and patient privacy, clinical technologies, GCP, General Data Protection Regulation (GDPR), security and compliance guidelines. As this innovative approach continues to gain traction, it holds the promise of transforming the way clinical trials are conducted, benefiting both researchers and participants in the quest for better health care solutions.

For more information on how to deploy clinical trial tokenization in your study, please contact www.ICONplc.com/tokenisation.