Biotech Innovation: Linking real-world data and patient insights to help demonstrate asset value

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What is tokenization, or data linking?

Tokenization refers to the process by which sensitive, personally identifiable information such as name, date of birth, gender, and zip code are replaced with an encrypted string of unique characters – also known as a token. Tokens can be used to securely match study patients in a clinical trial dataset across various types of real-world data sources, granting a more holistic picture of the full patient journey – putting patients first.

The scope of real-world data (RWD) included in clinical research typically faces shortcomings in informing researchers and sponsors of a patient's personal characteristics and their collective treatment journey and experience. For example, researchers and sponsors typically lack a full understanding of patient access to alternative treatment options or personal satisfaction and experiences with current therapy.

Parexel initiated a study protocol that aimed to evaluate technologies for linking participant insights with RWD to try to close this gap. With this initiative, we incorporated innovative data science techniques using streamlined technology integration and tokenization. These techniques demonstrated that we could link RWD in the form of medical records to a more complete and holistic view reported by an individual patient. Our goal was to better understand how patients respond to the treatment and gain more insight into the target population. This insight would help us identify a potential market and build a proof of concept demonstrating the value of the asset.

The initiative proved the viability of reaching out directly to a specific group of patients to gain their informed consent to complete a simple questionnaire about their health. Then, for patients willing to provide additional consent, we tokenized the data obtained via the questionnaire and linked it with that same individual's data in RWD sources.

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This approach enabled us to reach patients experiencing a specific disease (in this case, chronic heart disease being treated with anticoagulants) and connect RWD with confidential information about themselves, their circumstances, and their healthcare experiences. Our tokenization process used name, gender, and date of birth. Patients participated based on self-reported cardiovascular conditions, corresponding with the participants' diagnoses and treatments according to the linked external data. This suggests that our funnel to select a specific group of patients was effective and that patients report honestly – regardless of the compensation offered – when interacting with the study systems.

The Parexel team, in designing the patient questionnaire, had the foresight to include several questions that might not routinely be considered for a study. Because Parexel strongly supports diversity in clinical research, we included questions about race and ethnicity as well as social determinants of health (SDOH). These included questions about income, educational attainment, and the source of patients' healthcare insurance to identify a potential pathway to reimbursement.

What we learned about the patients

Insights from the patients include, for example:

- Their concerns about their current treatment relative to safety, efficacy, and affordability.
- The treatments they had tried previously.
- Social and familial pressures on patients that affect treatment adherence.
- Necessary improvements in patient communication.
- Patient experience of care coordination.

Potential applications of our approach

Besides its potential support for a proof of concept, we see many other applications of the approach used in our study. Examples include using the platform as:

- A pre-screener for participation in a specific trial.
- A virtual waiting room for patients expressing an interest in trial participation.
- A means of long-term follow-up, particularly useful with cell and gene therapies.
- As the basis for a natural history or burden of disease study.

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Conclusion

This study demonstrated that linking data through tokens allows us to gain valuable insights by complementing RWD and acts as proof of concept for the use cases outlined in this article. With data that relates to treatment experiences, preferences, and costs to the patient and that considers race, ethnicity, and SDOH, we can obtain a holistic view of patients who otherwise may be underrepresented. Customizing the Internet-based targeting and the series of questions in our direct-to-patient approach could help identify specific populations for research using RWD based on characteristics incomplete or absent from the RWD. In addition, from the study, we were able to deliver insights such as those related to patients' digital literacy and how to effectively manage latency in external datasets.

We believe that there are many other strong use cases for tokenization. Embedding it in a seamless direct-to-patient setting minimizes patient burden while facilitating further research directly with the patient by combining data we collect with external data sources. Using this approach, important questions can be answered about the health of enrolled participants. We can understand their treatment pathways and preferences, facilitate remote and long-term follow-up for endpoints and outcomes, as well as conduct post-authorization safety surveillance.

The know-how we have gained from this study and others of this kind prepares us well for innovative study implementation. With our success in achieving our vision through a blend of technology, effective vendor management, and patient-centricity, we look forward to extending these capabilities to our clients' innovative study challenges.

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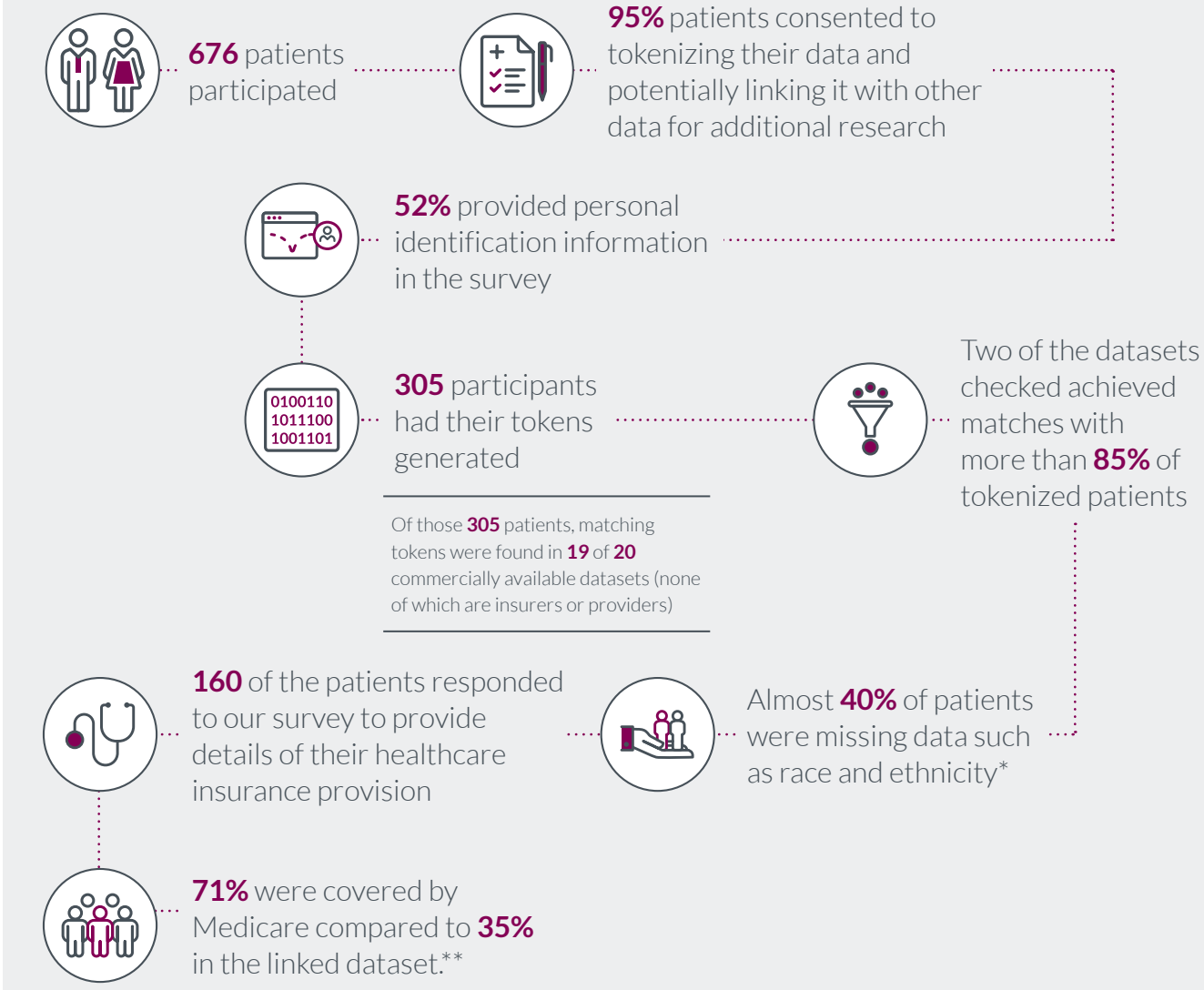
About our methodology

To achieve this proof of concept, Parexel managed and integrated the contributions of several of our partners to deliver our vision and created a seamless experience for the patient.



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*Collecting this information directly from patients adds richness to the combined dataset. The same applies much more broadly to other socioeconomic factors, such as education and income, which are usually absent from external datasets.

**By using the survey approach, we were able to represent a greater proportion of Medicare patients in our analysis.

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