Resolve: Parexel demonstrates data tokenization and linkage in a seamless direct-to-patient study

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Parexel®

What is tokenization/data linking?

A token - an encrypted string of characters - can be generated from personal information of a patient that securely and uniquely identifies that patient in a dataset.

If individuals agree before or after to that same tokenization process in other settings, then it becomes possible to use tokens to match data patient-by-patient across multiple data sources. This data linking makes possible a more holistic picture to help us put patients first.

What we did

We wanted to demonstrate that we could reach out directly to a specific group of subjects being treated with anticoagulants, ask them for their informed consent to complete a simple questionnaire about their health and, for subjects willing to provide additional consent, tokenize their data so that we could link the data we obtained directly from each patient with that same individual's data in real world data sources.

We believe that there are many 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 healthcare questions can be answered about the long-term health of enrolled subjects; we can understand their treatment pathways and preferences, and facilitate remote and long-term follow-up of subjects for endpoints and outcomes as well as post-authorization safety surveillance.

How we did it

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

Partner A provided IRB review of Parexel's novel study documents and was able to bring their knowledge and experience of tokenization and privacy to help us ensure a fit-for-purpose protocol.

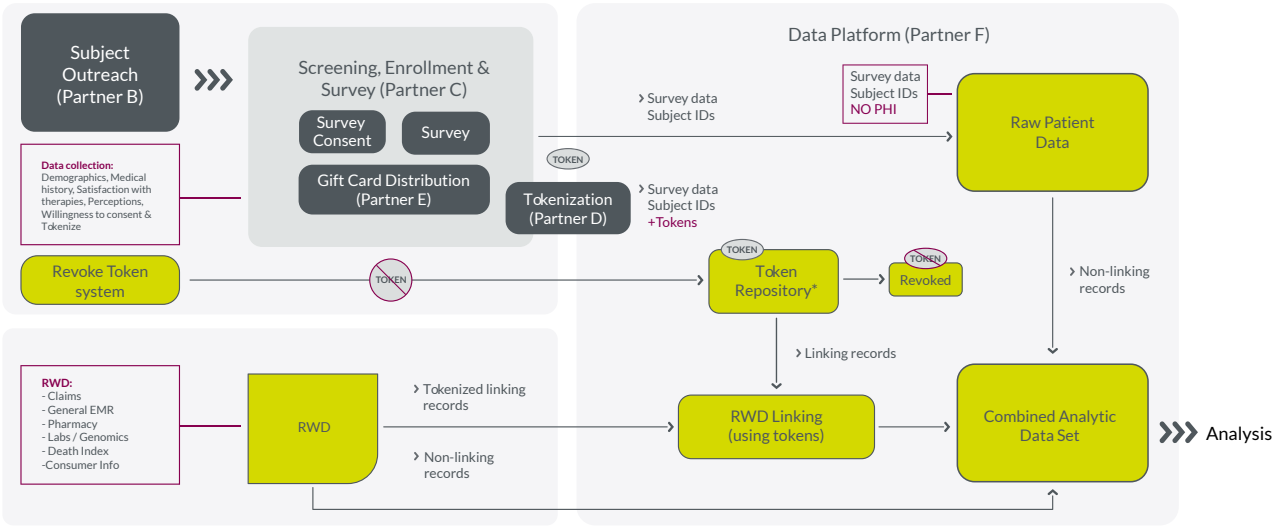
Partner B used their outreach techniques to pre-screen subjects for study suitability and, if they were suitable according to their responses seamlessly transfer them into Partner C's environment.

In the **Partner C** platform, the subjects were informed further about the study, and, if willing, provided consent and answered the questions that we had posed in our brief questionnaire. Further informed consent was sought for adding tokens for their data.

Partner D's tokens were generated from the information supplied by the subject within Partners C's platform.

Partner E provided compensation for the subjects' time and effort for the first 100 participants to complete the study with a gift voucher triggered from within the platform.

Finally, **Partner F** provided the data platform into which we transferred the tokens and questionnaire data in preparation for analysis at Parexel.



* Token Store is token-provider independent

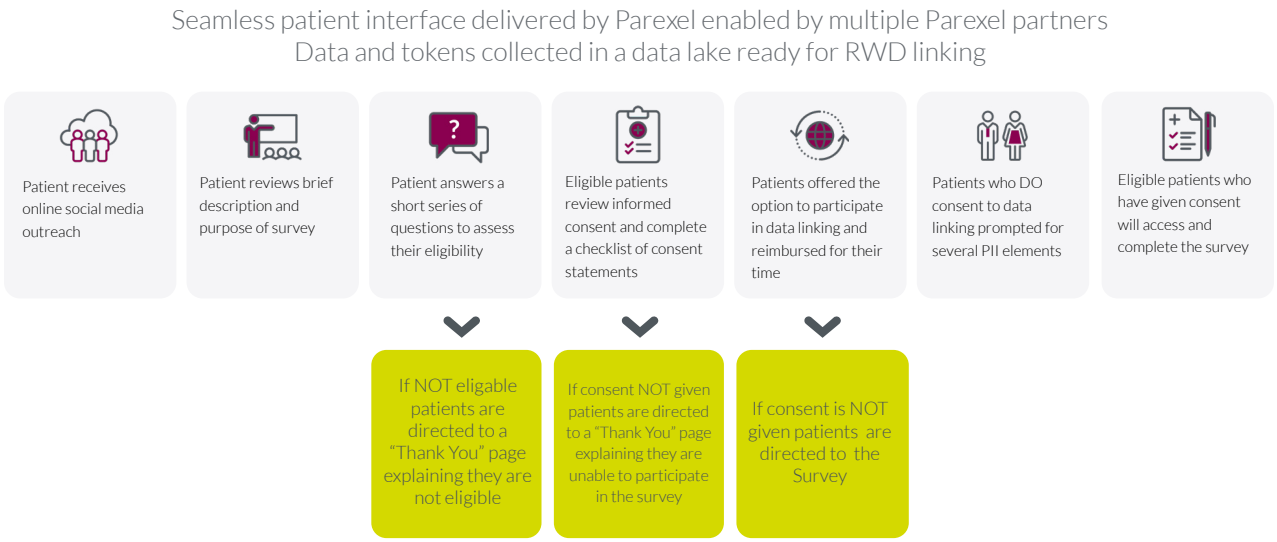
Data Flow for Resolve

What we found

We had a total of 372 subjects who participated in our study during the 40 days that the system was open to recruitment, and of these subjects, 305 (82%) consented to have their data tokenized and potentially linked with other data.

As we publish this whitepaper, we already know through using Partner D's tools that of the 305 volunteers who consented to tokenization and data linking, we found matching tokens in 13 of 17 commercially available datasets (none of which are insurers or providers). Of the datasets checked, two achieve matches with above 40% of Resolve subjects.

We plan to incorporate matched data into our analysis in the future, and we are very excited by the way that Resolve has already demonstrated the potential to contextualize the questionnaire responses obtained in our study with the longitudinal data that may extend both before and after the study for the subjects we enrolled.



Patient experience for Resolve

What capabilities we developed

A direct-to-patient study incorporating innovative data science techniques presents a number of challenges that Parexel has been able to solve, including:

- Seamlessly passing the patient from one environment to another within a single user-friendly interface.
- Explaining tokenization and data-linking in accessible language for volunteers.
- Facilitating token revocation should subjects wish to withdraw consent to linking the data.
- Making sure that whether subjects consented or decided not to proceed that the system provided appropriate appreciation and recognition in the direct-to-patient environment.
- Making sure that subjects were comfortable with privacy and providing reassurance that sensitive data used to generate tokens was secure and could never be accessed.

The know-how we have gained by sponsoring the Resolve study and our involvement in other innovative studies prepares us well for innovative study implementation. With our working knowledge of how the many challenges can be met, achieving our vision though a blend of technology, effective vendor management and patient-centricity, we look forward to extending our capabilities to our clients' innovative study challenges.

Benefits of our approach

Where does Parexel's agile and configurable approach as demonstrated in Resolve help us find solutions to research and development (R&D) challenges? It's possible to imagine that the approach applied in Resolve could demonstrate benefits in many situations including:

- Pre-screen patients for planned studies and 'pre-tokenize' patients expressing an interest in a study so that well before any clinic visits, they can fully digest information on tokens/data linking and, for example, consult family members prior to giving consent.
- If the approach is an entry point for a conventional site-based study or a hybrid of site-based and direct to patient, the removal of consenting to tokenization from the site activities helps sites focus on delivering care to their patients.
- Tokenization and its potential for data-linking within the direct-to patient construct has the additional benefits of facilitating (very) long term follow-up and can help reduce or even remove the costs of conventional follow-up.
- The approach can address commercial questions about patients' experience with products and compare to their treatment pathway before and after the direct-to-patient interactions. Equally it can help us better understand areas of unmet need for patients, natural history, and burden of disease. The type of approach we adopted in Resolve accomplishes these objectives in a way that is easy and convenient for a patient and allows them to be compensated for their time and effort when they are willing contribute to research.

With Heart™

We're always available for a conversation

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