Enabling data science to support cell therapy clinical trials

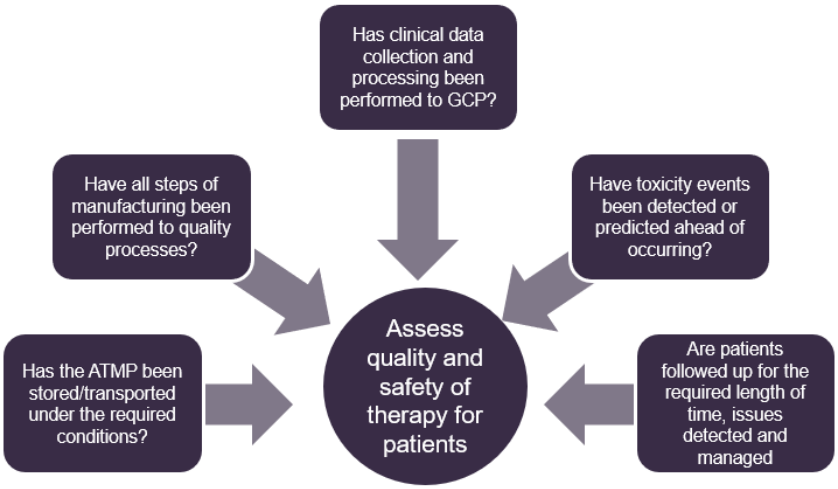
The challenge

Secure data and document management is essential in any clinical trial. This is to protect the integrity of the data and documentation generated as part of the trial and most importantly ensuring the confidentiality of the patients' information. The data and documentation gathered during a cell therapy trial is likely to be greater quantity than a conventional clinical trial and over a longer duration to meet regulatory requirements. Furthermore, data is gathered from multiple sources and requires standardisation to be utilised effectively and in full compliance with data protection regulations.

In addition, an increased volume of documents will be generated during the conduct of these complex clinical trials, therefore an effective and integrated document management solution is desired.

The value of data integration

- Common to all of these aspects is data collection and integration
- Data will be collected during the manufacturing process, during transport through to patient treatment and follow up
- Innovative analytical strategies such as AI could enable better detection of toxicity effects
- Data governance is key to enable exploitation



The solution

Establish an innovation hub consisting of:

1. A compliant platform to import and store raw data (Datatrial's Nucleus software).
2. Software to convert the raw data into a useable format (Formedix SDTM automation platform).
3. A set of secure data transfer mechanisms to automatically transfer raw clinical data from the source Electronic Data Capture (EDC) system within Nucleus.
4. Secure raw data transfer from Nucleus to Formedix, mapped into SDTM compliant domains. SDTM datasets are then transferred back to the Nucleus system.

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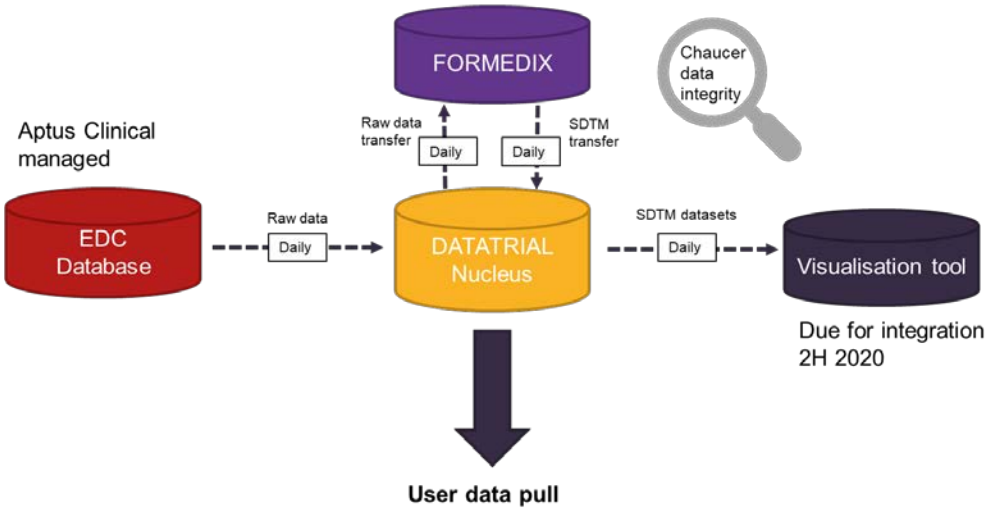
5. A new electronic Trial Master File (eTMF) system co-developed by Datatrial and Aptus Clinical in Nucleus.
6. Fit for purpose documentation and processes developed by Chaucer to ensure regulatory compliance requirements are met.

This innovative solution is intended to provide a cost effective and efficient solution for compliant storage and integration of data and documents used in early phase clinical trials and is currently being deployed in the exemplar study in the iMATCH project.

The results

Through a strong collaborative partnership, the iMATCH digital innovation hub has been created. This is a single clinical data ecosystem that can be used for compliant processing of ATMP data from clinical trials. It brings together several systems that are required from the starting point of electronic data collection through to standards management and conversion finally through to data repository and eTMF; essentially, a single one-stop shop that meets all the requirements of the clinical data processing lifecycle. The iMATCH digital innovation hub is being piloted in an ovarian cell therapy clinical trial due to open at the Christie hospital in early 2020.



Making further impact

As a result of their involvement in the iMATCH Project, Aptus Clinical has built an internal capability to deliver full clinical data management services. Datatrial have delivered updates to their Nucleus platform ahead of schedule, alongside integrating their eTMF into this. Several Aptus Clinical clients have chosen Nucleus as their eTMF solution for their clinical trials. Chaucer have enhanced their existing capabilities in clinical data governance to provide increased value to their existing and future Life Science clients. The Formedix platform now

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provides a fully automated SDTM conversion process. Formedix automatically pulls data from external sources (such as EDC), converts it into SDTM, then pushes SDTM datasets back to the client's system, presenting the data in a regulatory compliant manner.

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