

# P13 HARNESS THE DATA'S POTENTIAL IN A CLINICAL TRIAL



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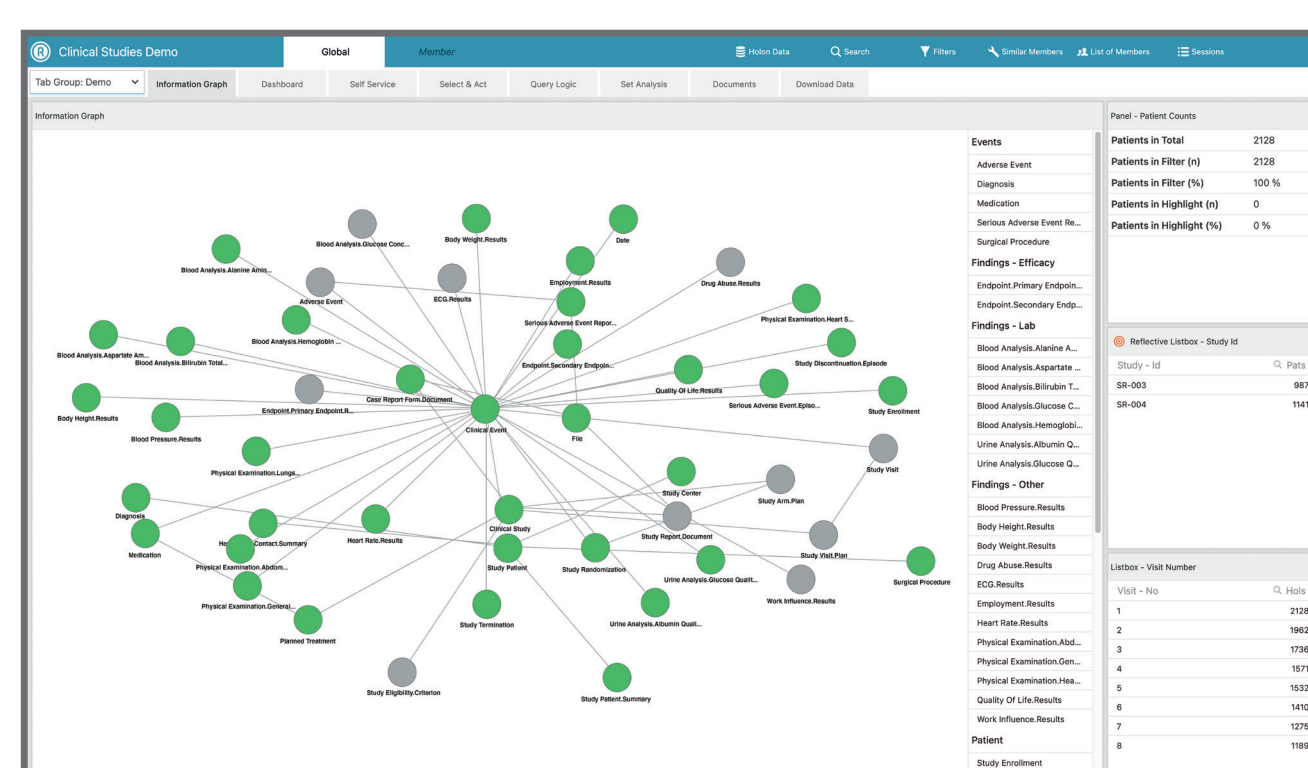
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**A FAIR REPOSITORY** is a good starting point for gaining a holistic view of the clinical trials performed in a drug development project.

To optimize data access and search capabilities, a repository must be meticulously organized and modeled. This involves integrating metadata seamlessly with the data and ensuring comprehensive annotation for every piece of information.

Utilizing a graph database proves to be a valuable tool for storing and navigating intricate and unstructured data, such as medical data.

Using this technology, the information model can easily be expanded as data from new areas is continually added when additional trials are included in the multiple trial repository.



An information model populated with data and metadata, i.e., a knowledge graph.

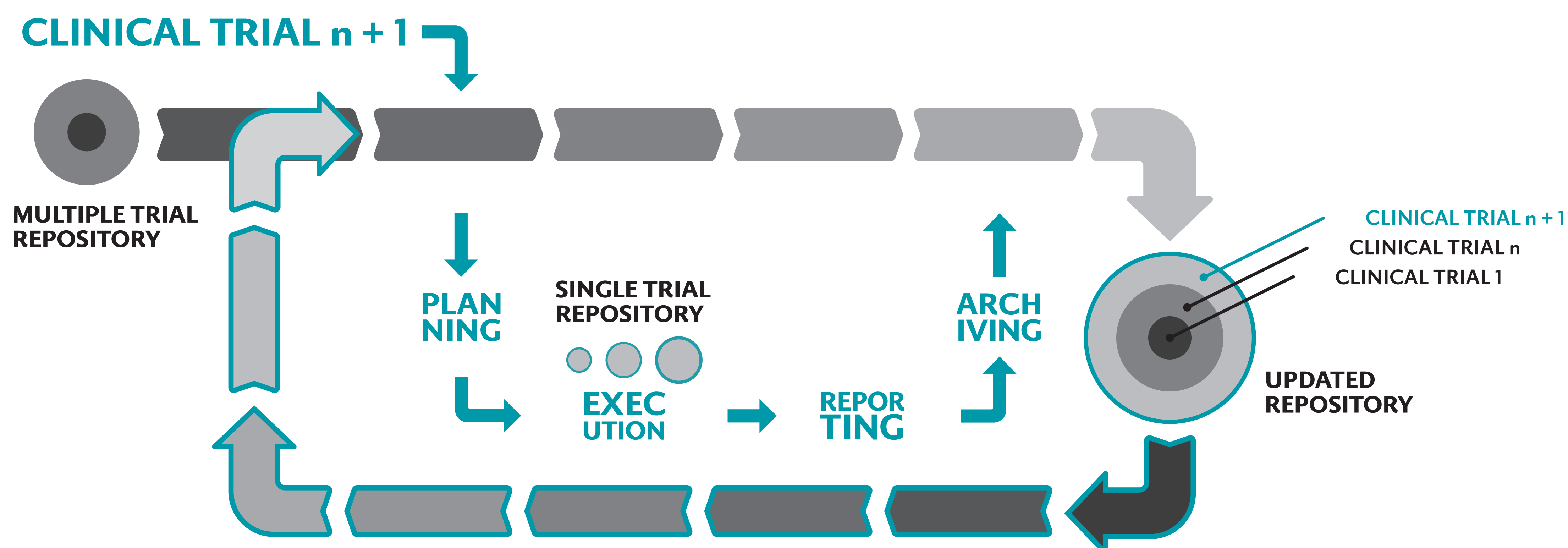
With an intuitive interface end-users can work with data throughout the clinical trial process in a single trial repository as the trial is ongoing.



A visualization for comparison between subgroups and discovering outliers.

Clinical Trials are essential for new drug development and the process contains different activities that can be summarized to planning, execution, reporting and archiving. Data is in the centre of each of these activities and thus data availability is crucial. Clinical trials are

collaborative efforts involving project members with different backgrounds and responsibilities e.g., project manager, data managers, statisticians, medical writers etc., who work with data in different ways and for different purposes.



## Effects of using a FAIR repository for clinical trials in different stages

### PLAN NING

Utilizing insights and learning from previous studies can contribute to efficiencies in the selection of study populations, patient recruitment and endpoints to be measured.

### EXEC UTION

With a trial specific repository project team members can access and gain insights by integrating data from diverse systems, including eCRFs, biomarkers, lab results, and PROs. This can contribute to increased data quality, efficiency, transparency, and early decision-making.

### REPOR TING

In the reporting stage, time can be saved by having access to all data in a holistic and comprehensive view when results should be explored, interpreted, explained, and understood.

### ARCH IVING

Clinical trial data is to be retained for a required period after the trial has been concluded. The completed trial should therefore be added to the multiple trial repository for later reuse.

Optimize the design

Quality Control and Data Monitoring

Holistic Data Access

Use & Reuse

COLLABORATION

### CONCLUSION

The ability to harness insights from data empowers e.g., researchers, analysts, and decision-makers to make informed choices, advance scientific knowledge, and drive improvements in various domains. When data is FAIR and easily searchable, collaboration will be facilitated, and the clinical trial contributes to extended value.

Artwork: Pierre Moreau, Capish