

INTRODUCTION

Challenges

Data drives the success of Pharma initiatives, and that success depends not only on the quality of the data, but also its usability. Data accessibility and usability are often limited by challenges such as:

- Large volumes of data
- Combining data sets for cross-study analysis
- Data structure that restricts further analysis and reuse
- Incorporation of real-world data

The unique challenges for this data-driven industry make data accessibility a paramount concern. Data scientists require an entirely new method and tool for the structuring of data, as well as rapid retrieval and relationship visualization. All data must be accessible all the time, to avoid delays of innovations and findings that may impact patients.

Pioneering Technology

In order to improve accessibility and usability of data from multiple sources it is curated, integrated, and stored in a property graph database. Capish has advanced the classic property graph database by using an ontology-based information model and by implementing several indices making the data querying process faster and more intuitive for the end user.

Reflective logic is a new method used to retrieve responses to queries formulated with a Reflection Point. The Reflection Point, such as "Patient", "Batch" or "Investigational Drug", allows the user to explore all related data.

ALL DATA - ALL THE TIME - AT YOUR FINGERTIPS

Answer Complex Questions

Optimized searching within the property graph database, allows the end user to pose complex questions directly to the database and instantly obtain results. Data can be explored in parallel from different perspectives, and it is possible to easily switch between them. When exploring data from a certain perspective, a reflection point, all data related is retrieved.

Use Case

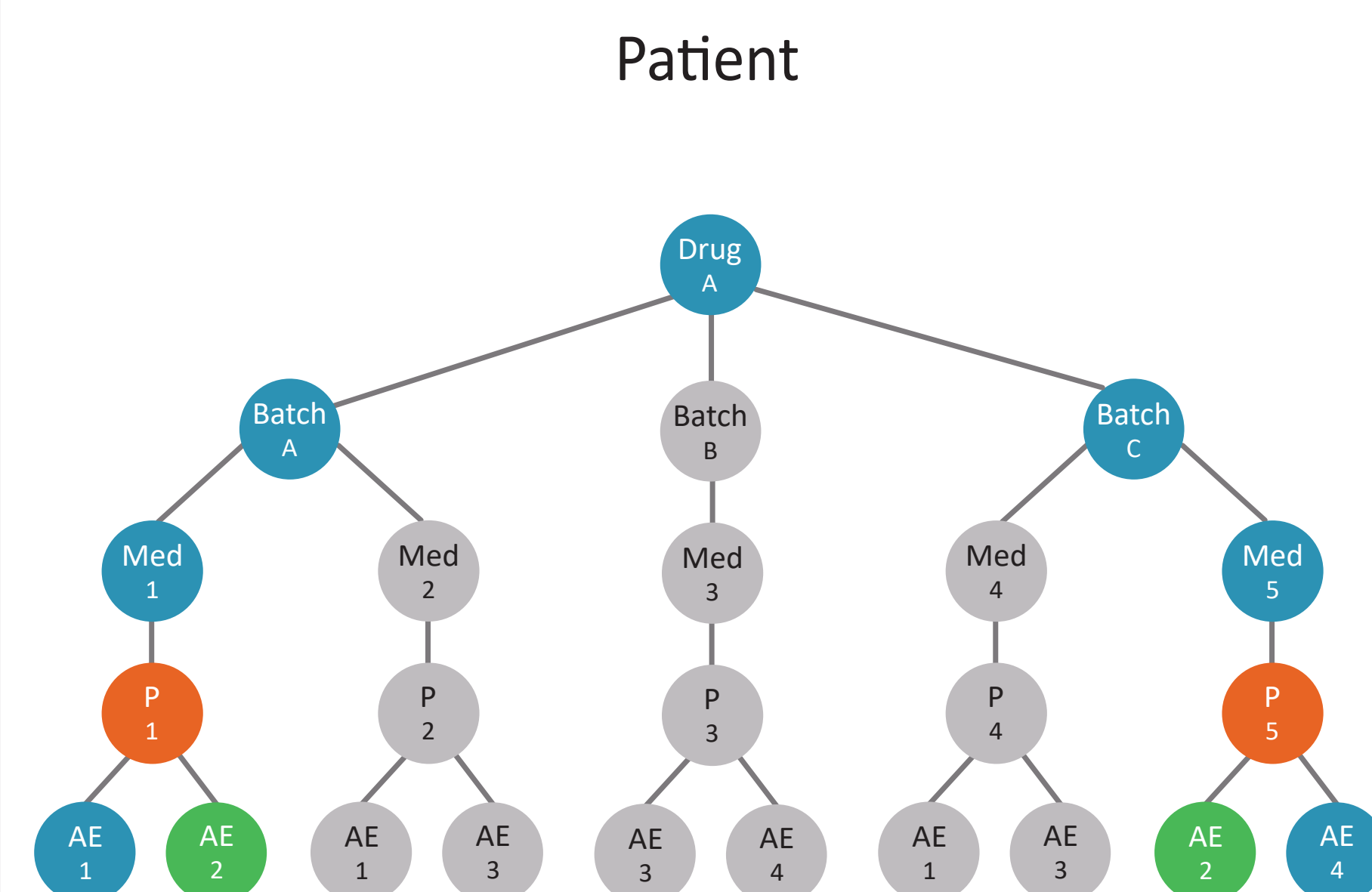
Consider ten clinical trials with the Investigational Drug A, produced in three different batches.

All trials are integrated into the same database.

A serious adverse event, renal failure (in the example below referred to as AE2), has been reported for several patients.

By having data already curated and modeled regardless of the question and utilizing different reflection points users can answer many different questions in a few clicks.

- = Holon in result
- = Holon matching query criteria
- = Holon not in result
- = Reflection Point Holon



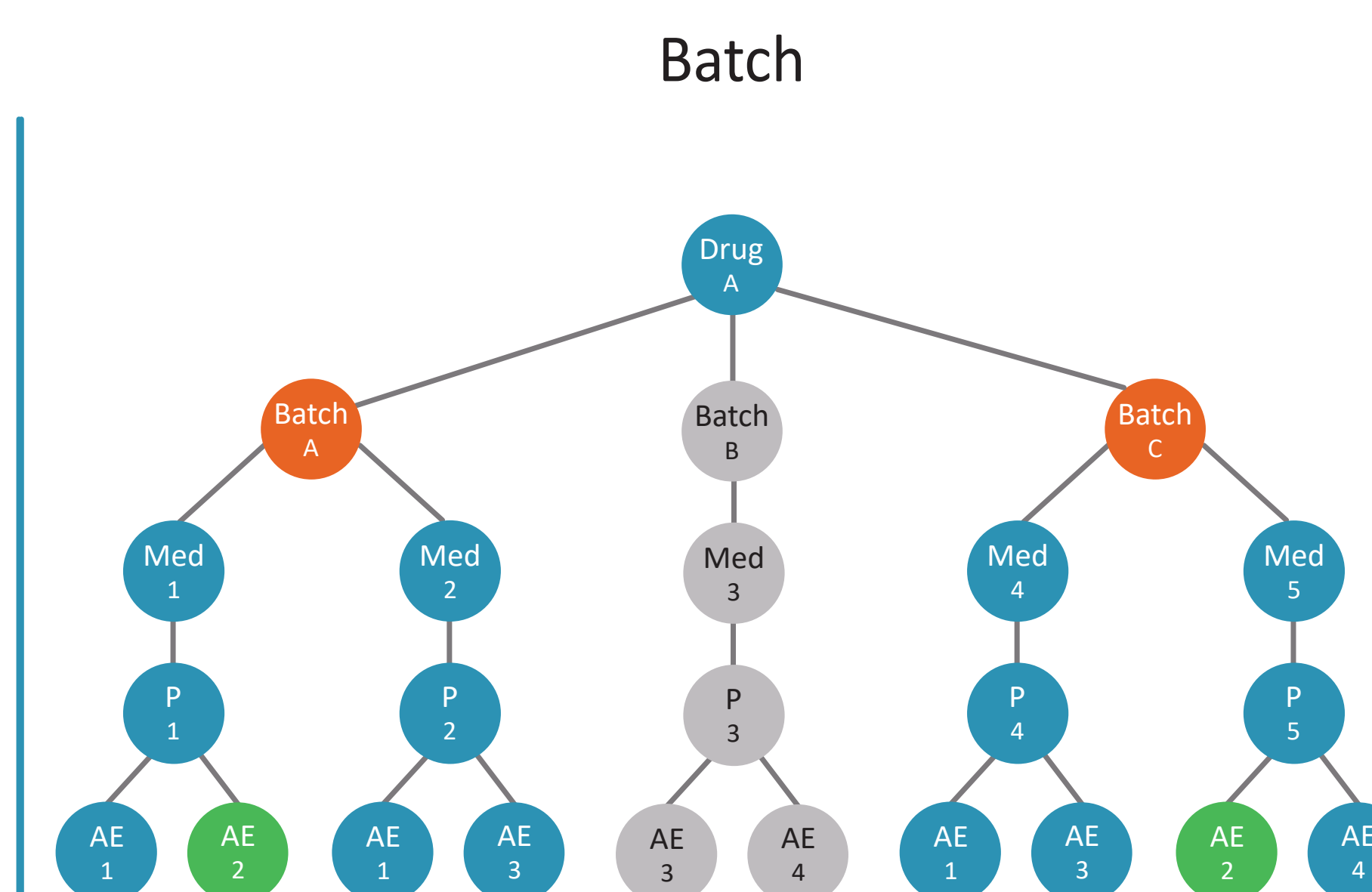
Reflection in Patient

All the AEs and all other data related to every patient having had AE2 is retrieved.

Reflecting in Patient will give the user an overall view of patients who have experienced renal failure.

Examples of questions are:

- What other AEs have been reported for patients who have experienced renal failure?
- What do these patients have in common (e.g. batch, site, concomitant medications)?
- Is there any difference in the incidence of renal failure between the different trials?



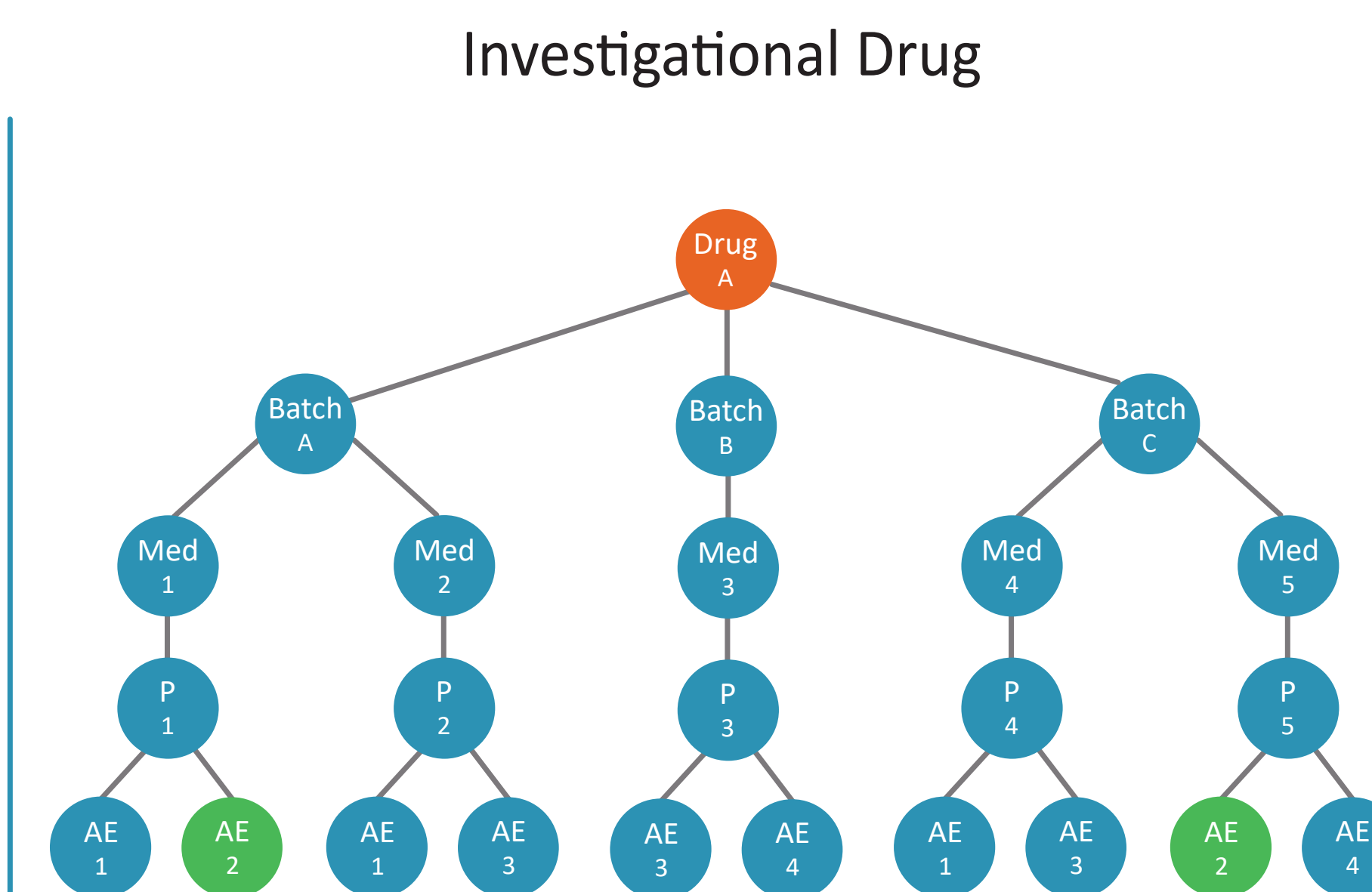
Reflection in Batch

All the AEs and all other data related to batches where AE2 has been reported is retrieved.

Reflecting in Batch will give the user an overall view of batches where renal failure has been reported.

Examples of questions are:

- What other AEs have been reported for batches where renal failure has been reported?
- Do patients, given the same batch as those with renal failure, have any evidence of elevated values that may lead to renal failure?



Reflection in Investigational Drug

All the AEs and all other data related to Drug A is retrieved.

Reflecting in Investigational Drug will give the user an overall picture of investigational drugs where renal failure has been reported. This means that all batches for all patients taking Drug A are retrieved.

Example of questions are:

- Is there any difference in the incidence of renal failure between the different batches?
- Is renal failure related to the drug or only to specific batches?

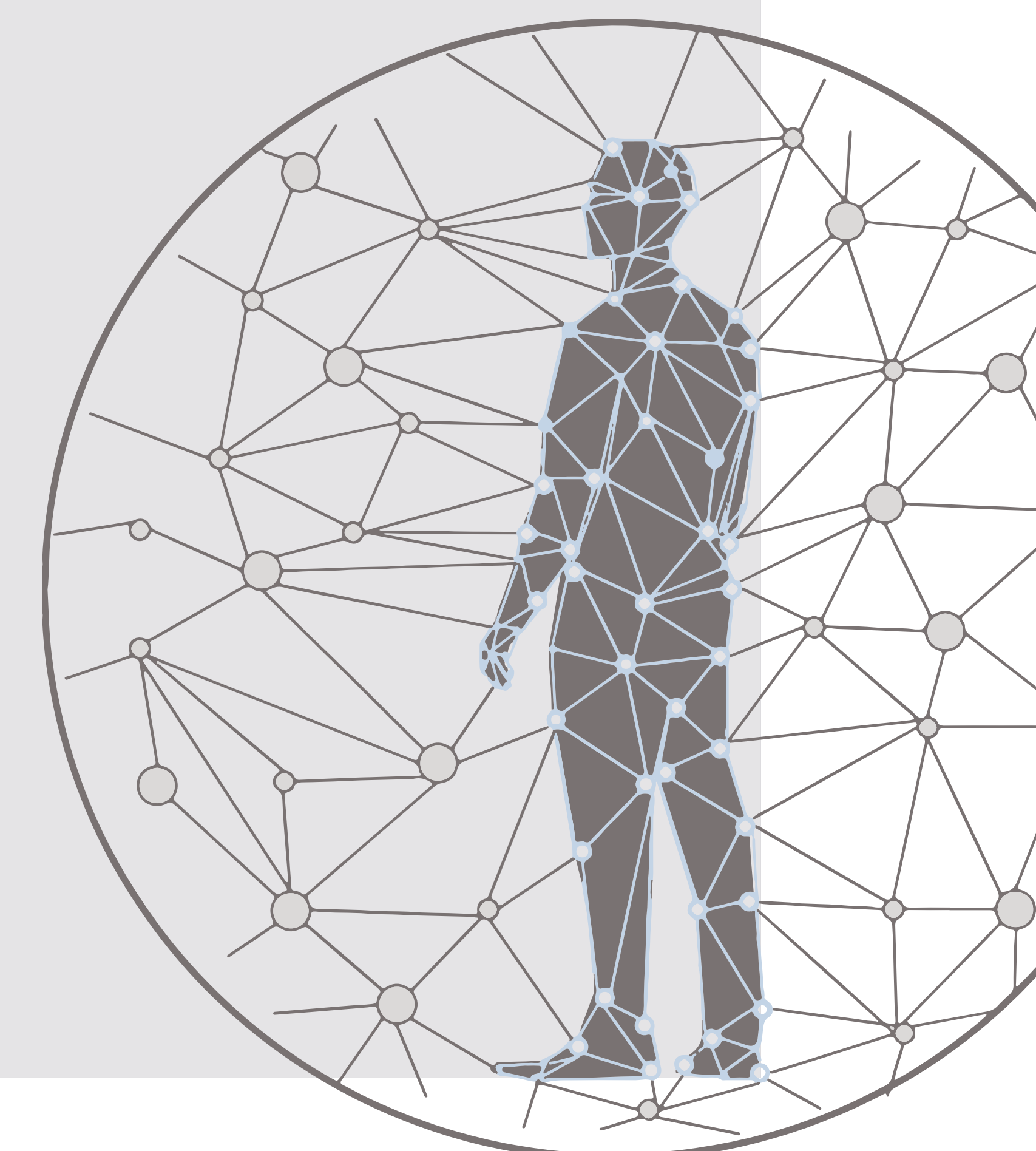
CONCLUSION

This approach is a breakthrough technology that allows immediate access to data and its relationships and the ability to answer complex questions in just a few clicks. Seamlessly analyzing data from different perspectives is possible using an ontology and a unique implementation of indices.

The underlying database is flexible and sustainable which allows users to easily access, combine, explore and enlarge datasets.

The ability to analyze all of the data related to e.g. the patient, batch, or drug and to quickly switch between the different perspectives provides for faster and more thorough analysis. This allows the data to be put to work for the greatest success.

This technology solves the problem of data accessibility and usability and the advantage of this approach grows with the complexity of the data and the questions. It delivers the power of all of the data to the user, all of the time.



Identified subgroups can quickly be compared to the whole population or to other subgroups to find if abnormalities exist in the subgroup.