**In silico Clinical Trial Feasibility Studies Using Real-World Evidence with Qiagram™**

Costly delays in clinical trials demand better upfront feasibility studies

Ninety percent of all clinical trials do not finish on time, resulting in cost overruns, loss of revenue, and perhaps failure of the trial. A leading cause for the delay is poor patient enrollment. Proper trial feasibility studies can help to address this problem by providing projections for various clinical trial operational parameters (enrollment period, number and location of sites, etc.) as well as other recommendations for successful study execution. The number of potentially eligible participants, estimated enrollment rate, and the operational feasibility of a new study are traditionally assessed through multiple information sources, such as data from ongoing or previously executed trials, outside consultants, personal experience, and surveys from hospitals.

**Rise of electronic health record (EHR) adoption**

In addition to the above traditional information sources, large patient data sets, such as EHRs, claims, and pharmacy data can also be used to identify eligible patient populations. Getting to the individual patient profiles may require chart reviews for determining detailed enrollment eligibility, which in turn may require complex arrangements with third parties that have direct access to the patient records. However, if the enrollment criteria are modest and/or can be gleaned from de-identified EHRs or other available electronic data sources, then eligibility projection can be estimated earlier and easier during the trial design process.

With the increasing integration of electronic health record systems by healthcare providers, policies being established to achieve meaningful use, and the growing availability of de-identified patient profiles worldwide, pharmaceutical investigators are now better positioned to leverage this treasure trove of information to aid trial design and feasibility analyses.

**What is Qiagram, and how can it help you?**

Qiagram is a unique and intuitive business intelligence software that seamlessly communicates with multiple data sources, allowing its users to pose ad hoc questions by drawing diagrams in a web-browser interface. As the visual reflection of a user’s thought process, these diagrams drive the underlying database search engine to return tailored results to complex queries, such as matching patient profiles using detailed trial protocol inclusion/exclusion criteria.

Qiagram is different from other database software search tools in its ability to help non-programmers (such as study physicians, epidemiologists, trial coordinators, project managers, and research scientists) to explore and make sense of important information from very large and complex data sets, such as longitudinal EHRs and claims data. Qiagram enables key clinical trial personnel to logically inspect and reduce the complexity of such data sets in a directed, stepwise fashion, resulting in more manageable and relevant subsets of data that are contextually meaningful and actionable.

**Using real-world evidence to optimize clinical trials**

EHR system implementation is fundamentally driven by its primary function of supporting healthcare. However, EHRs also provide tremendous “secondary use” value in, for example, supporting pharmaceutical R&D efforts such as clinical trial optimization and comparative effectiveness studies.

While traditional business intelligence strategies can create reports on standard, pre-defined questions, the creative nature of trial feasibility studies requires a much more flexible solution. This solution must allow the investigators to directly and rapidly interrogate all the supporting data to manipulate, compare, and simulate trial parameters as they formulate different trial scenarios. The result is an optimal set of parameters that facilitates successful, on-time enrollment.

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Example Application for Qiagram

A pharmaceutical company wants to evaluate the potential impact by each inclusion and exclusion criteria of a diabetes trial protocol on patient recruitment. Traditionally, this could be an expensive and time-consuming project which might only result in subjective and inaccurate information. Increasingly, information can be obtained from additional data sources that are more precise and objective, based on real-world evidence.

**Example EHR database of Type II diabetes patients**

1000

**Inclusion criteria**
- Dx of Type 2 Diabetes within last year
- Age between 18 and 74 years old
- Rx for pioglitazone
- Rx for metformin
- HbA1c ≥ 7.0 and ≤ 10.0%

**Exclusion criteria**
- Any historical Dx of Type 1 Diabetes
- Any history of pancreas injury
- Any history of acromegaly or Cushing’s Syndrome

**Patients filtered by trial criteria**

128

With appropriate access to de-identified EHR, claims, pharmacy, and other healthcare information sources, trial feasibility investigators can directly query their entire data collection using Qiagram’s unique drag & drop interface. Within minutes, they can determine real-time statistics on eligible patient populations, re-assess trial criteria impact, run detailed ad hoc reports, and much, much more.

![Qiagram](image-url)