DCRI **REAL-WORLD EVIDENCE**

A New Era of Clinical Trials

The promise of real-world evidence (RWE) is its ability to uncover a range of experiences that no single physician or group of physicians could amass in a lifetime of practice. The DCRI is leading the movement to harness the potential of RWE to improve drug development, product use, and delivery of precision medicine. Utilizing rigorous, best-in-class tools and mathematical algorithms, our renowned biostatisticians and data scientists are ushering in a new era of pragmatic clinical trials.

THE RIGHT APPROACH

There is a tendency among those leveraging RWE to start with the data and then formulate the question to fit the available parameters. This approach can lead to biased trial design, missed opportunities, and results with a narrow frame of therapeutic application. The right approach is key to achieving results with a broad impact. At the DCRI, our pathway to achieving meaningful analytics is to:

Ask the right questions

Find the right data

Apply optimal methods

Arrive at an impactful decision

PUTTING THE 'REAL' IN REAL-WORLD EVIDENCE

The evolving nature of RWE demands not only deploying existing analytical methods appropriately but creating new ones as well. The DCRI has the proven expertise to find patterns within datasets that lead to stronger and more actionable insights. Our approach of framing the right question and then applying optimal methods informs our work in:

- Clinical trial design and risk-based monitoring
- Independent data monitoring support
- Clinical trial statistics
- Patient preferences and patient reported outcomes
- Health economic research
- Outcomes research statistics
- Comparative effectiveness research
- Predictive analytics

Expertise in Practice

The DCRI launched the first and largest cardiovascular clinical registry, the Duke Databank for Cardiovascular Disease, in 1969. Since then, we have designed and managed more than 1,000 clinical trials across the globe. The DCRI continues to manage some of the largest and most prestigious registries, while conducting research using a wide variety of health data sources, including:

Electronic Health Records (EHRs)

Large Epidemiological Cohorts

Clinical Trial Data

Registries

Observational Prospective Studies

Medical Claims Data

Digital Health Data

Custom Dataset Aggregations

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Find out more about Real-World Evidence at the DCRI.

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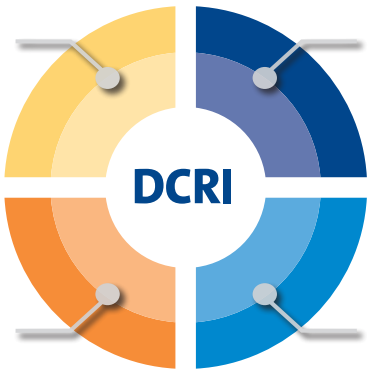
DUKE'S NETWORK OF PARTNERS

The DCRI's partnerships with other Duke Health faculty and institutes, as well as organizations such as PCORnet and CTTI, exemplify our approach to clinical research. Beyond Duke, the DCRI has partners across 37,000 sites in 65 countries. These alliances put us at the center of the health information universe.



HEALTH INFORMATION COMPANIES, SOURCES

Athena Health, Cerner, EPIC, Flatiron, IBM Watson Health, Optum, Vivli

HEALTH INFORMATION USERS

Advisors, Clinicians, Healthcare Systems, Insurers, Patient Groups, Payers, Regulators

OTHER INTERESTED GROUPS, COMPANIES

ACC, AHA, AHIMA, AMIA, CTTI, ISPOR

PHARMA, DEVICE COMPANIES

Akili, Amgen, GSK, Merck, Pfizer, Regeneron, Sanofi

**This is not a comprehensive list of the organizations and users within the DCRI network of partners.*

USING RWE TO EXTEND CLINICAL RESEARCH

The DCRI uses RWE to extend knowledge generated by randomized clinical trials. These approaches can do more with what is most valuable in each source of evidence while minimizing their limitations.

EMBED

The randomization at the heart of a traditional clinical trial can be embedded into routinely collected observational data.

MIMIC

Observational data can be used to mimic randomized clinical trials using newer statistical methods, such as overlap weights and longitudinal matching.

TRANSLATE

RWE can be used to translate results from a traditional clinical trial into a specific population, such as the patients of a particular health system, using EHRs. This approach uses clinical trial data to estimate the effect of a drug, for example and uses EHR data to set a target population different from the trial population. Harnessing machine learning allows for effect projections to be derived for the drug in the unique population.

SIMULATE

By synthesizing cohorts through EHRs, DCRI can enhance the cost-effectiveness of full-blown trials, for example, by projecting experiences in phase III of a trial based on its phase II data or by determining the impact on the effect size of different enrollment patterns.

Duke Clinical Research Institute | FROM **THOUGHT LEADERSHIP** TO **CLINICAL PRACTICE**

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