TARGET PharmaSolutions

NISS Virtual Industry Career Fair

Richard C. Zink, PhD
Senior Director, Data Management and Statistics
TARGET PharmaSolutions
rzink@targetpharmasolutions.com

My Background

- Education
  - BS in Mathematics (University of Maryland Baltimore County)
  - MS and PhD in Biostatistics (University of North Carolina at Chapel Hill)
- Work
  - Internship at National Institute on Aging at National Institutes of Health (government)
  - Research assistant and consultant at UNC (academia)
  - Bristol-Myers Squibb (large pharmaceutical company)
  - Inspire Pharmaceuticals (small biotech company)
  - JMP Life Sciences, SAS Institute (software company)
  - TARGET PharmaSolutions (data company)
- Other
  - Adjunct Assistant Professor of Biostatistics at UNC-Chapel Hill
  - Associate Editor for *Therapeutic Innovation and Regulatory Science*
  - Past-Chair, Biopharmaceutical Section of the ASA

Introduction

The Cost of Clinical Trials

- Clinical trials are expensive
  - Tufts Center for the Study of Drug Development
  - $0.8 billion USD in 2000
  - $2.6 billion USD in 2013
- If study costs continue to rise at the current pace, clinical trials to establish efficacy and tolerability will become impossible to conduct
- Making drugs unavailable for areas of unmet need
- Stifling innovation in established treatment areas
- Placing an extreme price burden on consumers and health care systems

Real-World Data (RWD)

- Utilize available data sources
  - Electronic health records
  - Claims data
  - Patient registries
  - Pharmacovigilance databases
- Answer questions of regulatory importance more quickly and cost-effectively for a larger body of patients than those seen in clinical trials
- Issues with data quality and structure, selection-bias
- Selection-bias managed through propensity weighting, matching, stratification

Real-World Data (RWD)

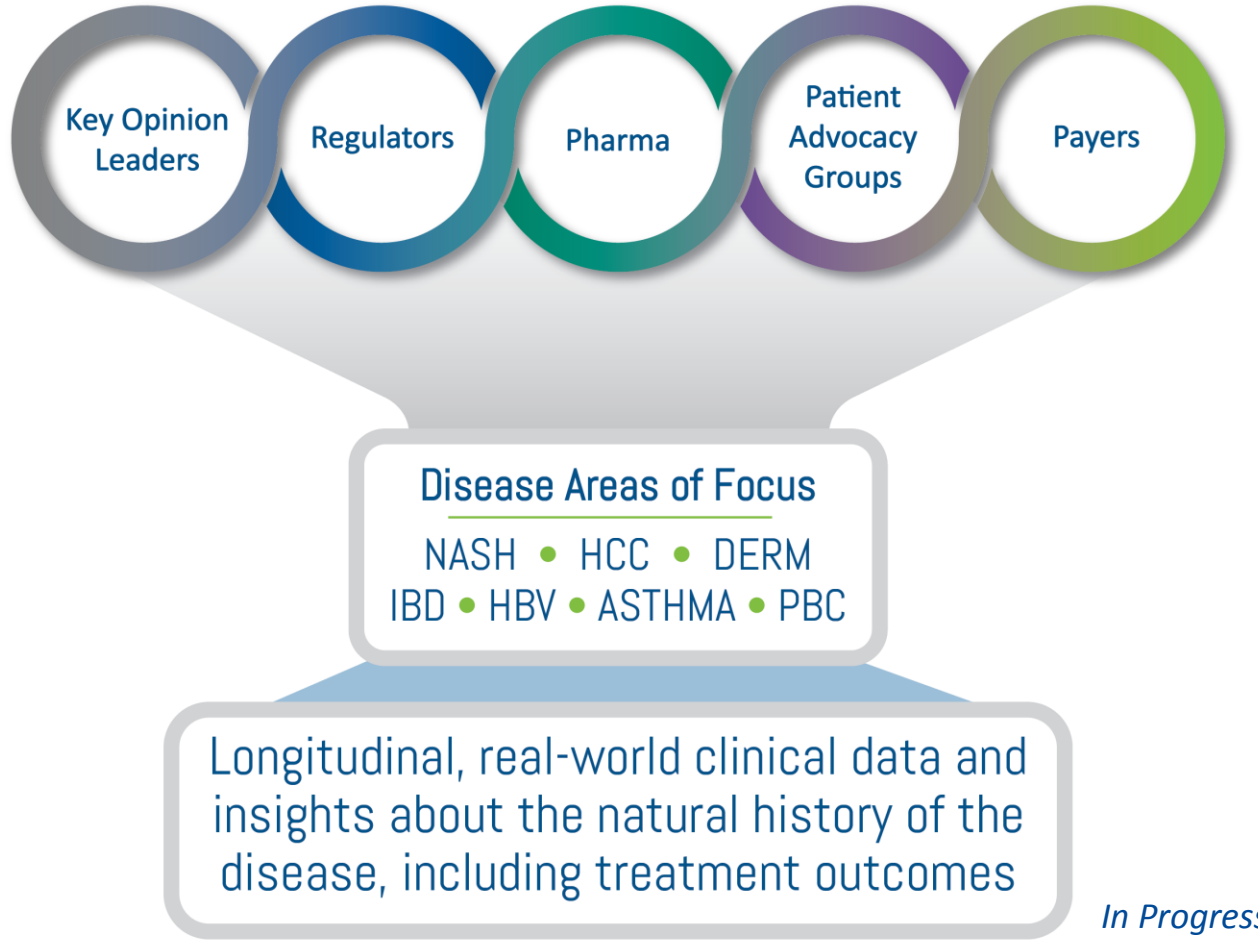
- 21 Century Cures Act (2016)
  - Support the approval of new indications for approved drugs
  - Support or satisfy post-approval study requirements
- Framework for FDA's Real World Evidence Program (2018)
  - RWD are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources
  - RWE is the clinical evidence about the usage and potential benefits or risks of a medical product derived from RWD

Overview of TARGET PharmaSolutions®

TARGET PharmaSolutions®

TARGET creates turnkey real-world evidence communities that generate data and deliver insights

Organizes a community of key stakeholders around a specific disease



In Progress: COVID-19

Bridging the Gap Between RWE & RCT

Real-World Evidence

Uncontrolled Confounders

Data Gaps

Variable Data Quality

Randomized Controlled Trials

Narrow Inclusion & Exclusion Criteria

Long Timelines

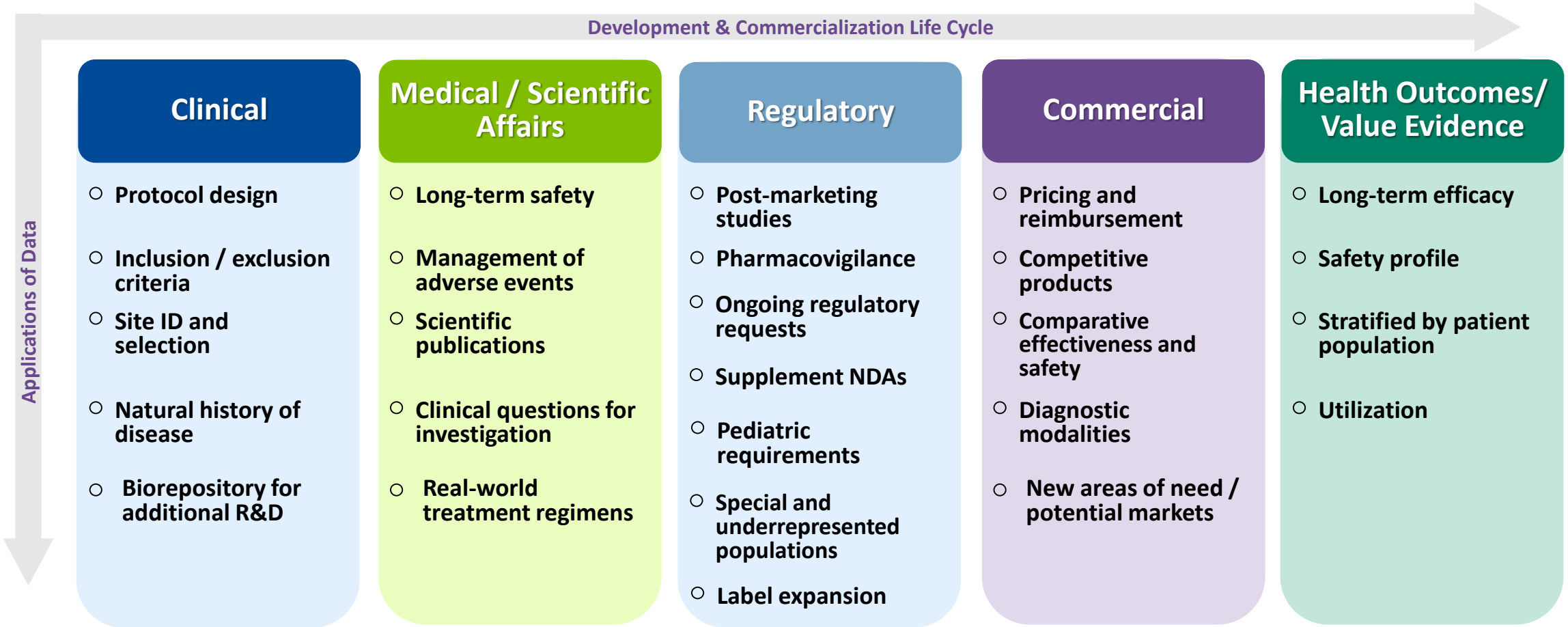
Not Representative of the Real-World

The TARGET Difference

- ✓ **Strict academic oversight**
- ✓ **Protocols designed by disease experts**
- ✓ **FDA *CRADA***
- ✓ **Evidence from real world practice**
- ✓ **Patient diversity**
- ✓ **Regulatory grade data quality/standards**
- ✓ **Matched biobank basic research**
- ✓ **Peer-reviewed publications**
- ✓ **Clinical practice guideline development**
- ✓ **Integration of multiple data sources**

Applications for TARGET's RWD

TARGET's RWD can be applied across the drug development and commercialization spectrum



Opportunities for Statisticians and Data Scientists

Unique Intersection(s)

- Industry, Regulatory, Academia
- Observational studies and RCTs
- Data from multiple sources
- A host of data and analytical challenges to appropriately analyze, interpret, and report data to address questions related to a particular disease

Primary Responsibilities

- Quarterly Reports
  - Provides an overall snapshot of study progress
  - Enables interactive visualization tool
- Publications
  - Abstracts to major conferences for posters and presentations
  - Manuscripts
- Confidential Queries
  - Asked by individual companies to answer a specific question of scientific interest
- Other
  - Data Linkage and de-identification

Query Example Overview

Natural History of Disease Analysis

- Incidence and prevalence of specific disease characteristics in various populations
- Frequency of disease-specific procedures or assessments
- Frequency of medication use in various subgroups
- Average intra-subject variability of laboratory assessments or findings from other procedures
- Disease progression (e.g., cirrhosis to decomp., cirrhosis to death etc.)
- Analysis of payer mix based disease severity
- Summarize the presence of specific safety outcomes

Biospecimen-Related Analysis

- SNP Genotyping Analysis
- Analysis of serum samples within a window of a disease-specific procedure
- Correlation of biomarkers with liver biopsy staging, diagnoses, events

Drug-Specific Analysis

- Healthcare utilization broken down by treatment course
  - Temporal ordering of drug classes
- Recommended vs escalated or reduced dosing
  - How patients are treated over time
- Assess changes in treatment relative to specific regulatory actions
  - Treatment types in conjunction with disease

Skills

- Statistics
  - Methods for observational data
  - Categorical and survival analysis
- Programming
  - Languages: SAS, R, Python
  - Data standards (e.g., CDISC)
- Soft skills
  - Technical writing
  - Public speaking
  - Presentation skills
  - Improvisation?

    (See what the New York Times, PRI, AAAS, and Science Friday have to say)

Wrapping Up

Final Thoughts

- A lot of opportunity at TARGET PharmaSolutions to engage intellectual and technical muscles
- Great deal of exposure to many facets of the medical product industry
- Greater understanding of patients who may not be well-represented in typical clinical development

Some Practical Advice

- Possible to switch between industries depending on how you conduct your career
  - Methodological research and teaching short courses makes it easier to switch to academia
  - Experience at the FDA makes you very attractive to pharmaceutical companies
  - CROs make it possible to achieve a diversity of experience quickly
- Jobs descriptions are written for the perfect candidate who often doesn't exist
- Update your curriculum vitae (CV) in real time, not when looking to find or switch jobs