Public-private partnerships to support post-marketing clinical research in routine care settings

National Cancer Policy Forum Workshop: Optimizing Public-Private Partnerships for Clinical Cancer Research

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Disclosures

Employment by Flatiron Health, Inc., an independent subsidiary of the Roche Group

Equity interest in Roche

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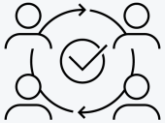
Public - Private Partnerships Require:

- Shared interest in the evidence

- Both entities provide essential contributions



- Broad stakeholder appreciation of partnership

Public = non-profit

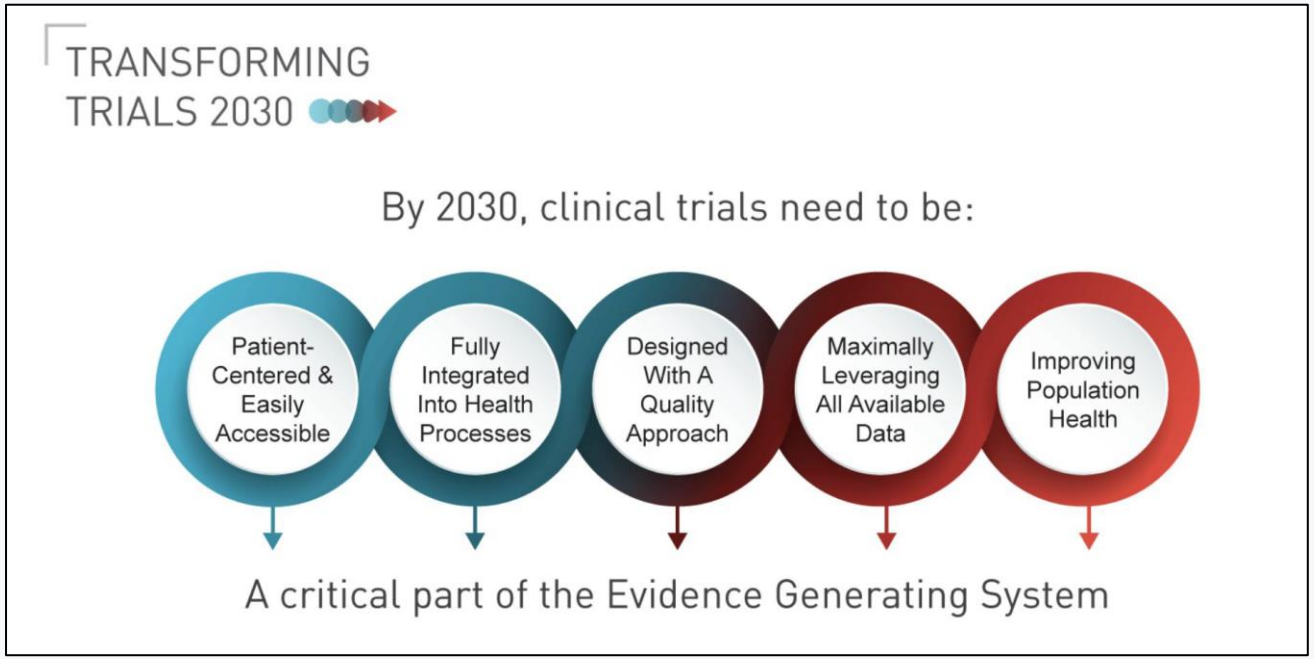
Private = for-profit

A Practical and Moral Imperative to Increase Access to Clinical Trials in Routine Care Settings

- The need for evidence is growing
- Clinical trials lack representativeness
- Most cancer patients are cared for in community settings
- Most clinical trials take place disproportionately in academic medical centers
- Community practices often lack sophisticated clinical trials support infrastructure
  - Training, staff, desire

➔ **Enabling clinical research in community practices and other non-participating settings (i.e. improving access) is needed to generate evidence and ensure participation of historically underrepresented populations**

CTTI Transforming Trials 2030



Clinical_Trials_Transformation_Initiative: https://ctti-clinicaltrials.org/who_we_are/transforming-trials-2030/#_ftn1

Public-Private Partnerships can support efforts to make trials more representative

Why now?

- FDA
- Legislation

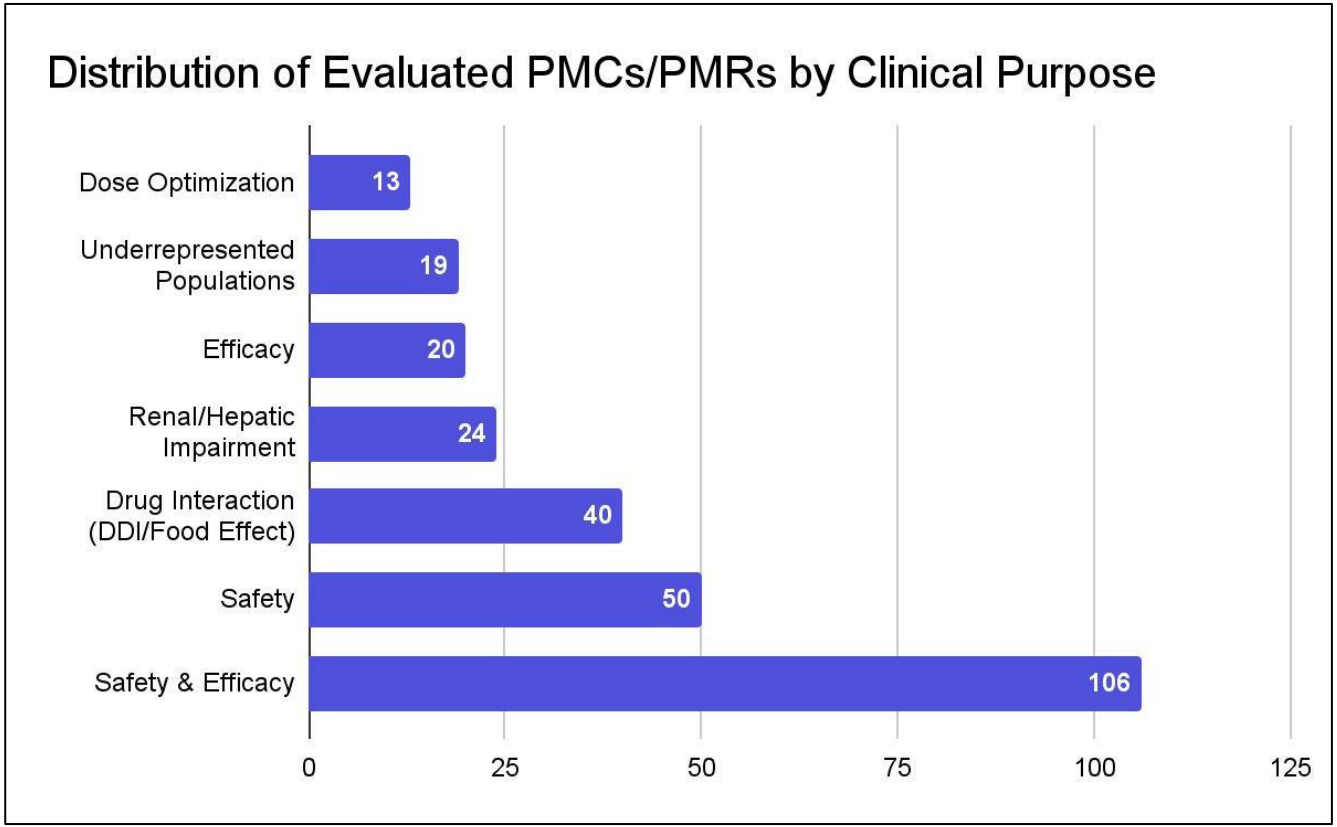
How?

- Utilize public / non-profit consortia infrastructure
- Support training
- Reduce regulatory hurdles for sites / investigators
- Simplify study designs
- Enable sites through technological innovations to identify and enroll patients, and collect data

Why are post-marketing studies especially suitable for routine care settings?

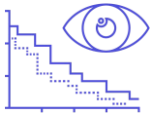
- Adverse event profiles are well-characterized
- Clinician-investigators have comfort level with treatment
- Pragmatic design elements may be aligned with routine care workflows
- Objectives may be highly relevant to practice
- Infrastructure requirements more limited than pre-market studies
- Patient burden may be modest

Regulatory Setting – PMCs/PMRs
FDA Oncology Approvals 2020-2022



Shiell et al. DIA 2023

Shared Goals for PPPs in Postmarketing Setting*



Treatment insights

- Effectiveness in broad populations
- Clinician / patient decision making
- Patient experience

Biomarker exploration

Practice patterns and access

- Resource utilization, economics
- Patterns of care
- Healthcare delivery

Precompetitive studies with honest broker

*regulatory + non-regulatory

The optimal features of studies suitable for routine practice settings

- Simple eligibility criteria
- Common diseases
- Low data collection burden
- Low patient burden
- Bring value to practice and patient

Pragmatic design,
Decentralized operational elements, and
Automated processes wherever possible

Types of Contributions

"Private" contributions

- Scientific muscle
- Money
- Infrastructure / resources
- Products (e.g. data, medicines, software)

"Public" contributions

- Scientific muscle
- Clinical / workflow insight
- Relationships
- Reputation
- Unbiased / unconflicted collaborators
- Infrastructure / resources
- Access to the real world (representative patients, process)

New technologies can streamline data collection
Example: Beat AML® Master Trial - Leukemia and Lymphoma Society

- Biomarker-driven platform for exploring new treatments in patients with AML
- Screening >> Assignment to phase 1b/2 substudies
- Technologies include EHR-EDC data transfer (Flatiron Clinical Pipe™), remote monitoring with source document upload, and rapidly customizable EDC (Flatiron Vessel™)
    - Automated data transfer from EHR
    - 6% increase in data accuracy vs. manual data entry
    - 60+ protocol amendments
    - 80% of monitoring remotely
    - >300,000 pages of source documentation

https://clinicaltrials.gov/study/NCT03013998

Routine Care Use Case: Registries

- Prospective observational studies
  - May include intentional data collection to standardize cohorts and outcome measures, minimize missingness, or additional non-routine assessments (e.g. PROs, exploratory biomarkers)
- Data of interest to multiple stakeholders (public and private) who could share infrastructure, enrollment, and data collection costs
- Enables long-term followup
- Leverage existing consortia infrastructure
- “Low” lift for study sites and patients, pragmatic
- Could support learning healthcare system with real-time curation and analytics
- Technology enablement: study design, site-selection, patient ascertainment, data collection

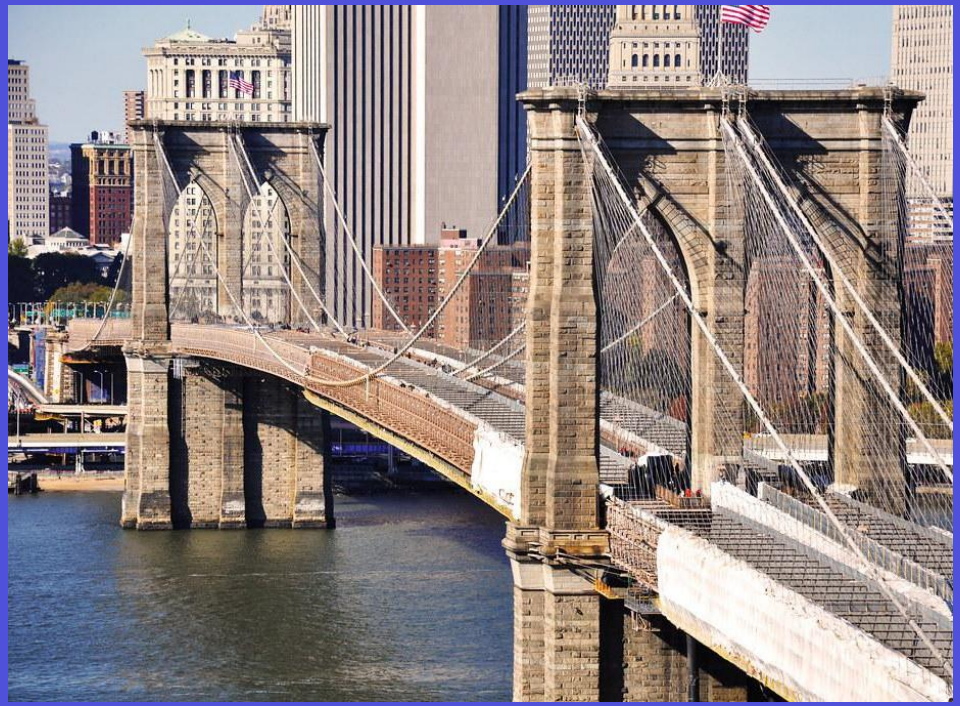
Change is really hard

- Heavily regulated context
- Stakes are high
- Stakeholders are risk-averse
- Systems / approaches are entrenched

The opportunity is great

- ☑ Focus on diversity and representativeness (FDA, legislation)
- ☑ Growing appetite for pragmatic approaches at FDA, NCI
- ☑ Availability of digital tools to simplify operational burden for sites and patients

Clinical studies in routine care settings are REQUIRED if we wish to bridge the gap between research and practice

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