



Facilitating Clinical Trial in Under-Resourced and Rural Areas: A Sponsor's Perspective

Challenges • Opportunities • Partnerships for

Ruma Bhagat MD MPH
Executive Director, Head of Strategy, Population Science
Genentech, A member of the Roche group

The Imperative: Why We Must Go Beyond the Urban C

- **Scientific Need:** To ensure our research findings are generalizable and applicable to a diverse patient population.
- **Ethical Obligation:** To address health disparities and provide equal access to promising new therapies.
- **Business Opportunity:** To accelerate patient enrollment, increase trial efficiency, and reach new markets.
- **Regulatory & Public Pressure:** Growing emphasis from FDA and public health advocates on increasing diversity in clinical trials.



The Core Barriers

Long travel distances,
lack of transportation,
time off work.

Financial burden on
patients, lower health
literacy, limited digital
access.



GEOGRAPHIC



INFRASTRUCTURE



SOCIOECONOMIC

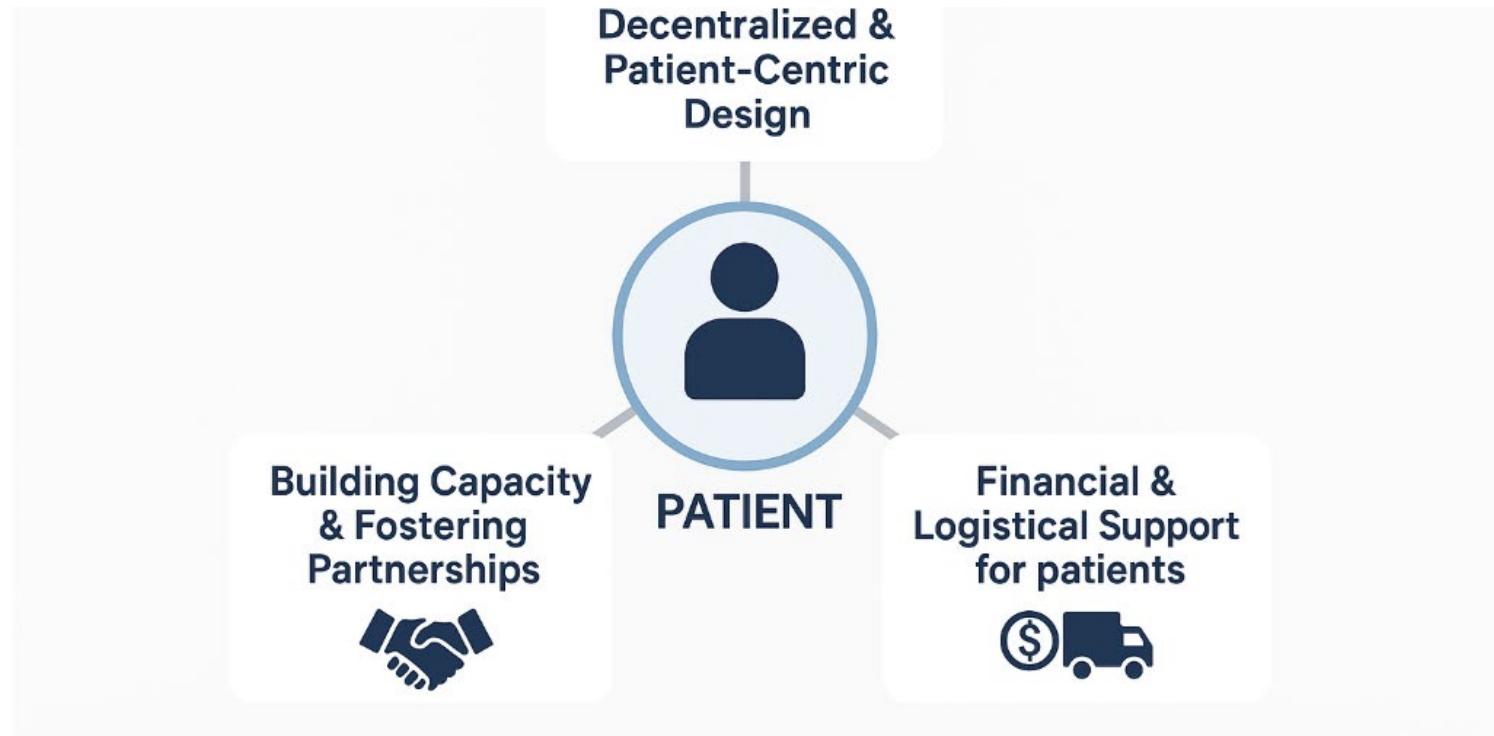


CULTURAL & TRUST

Research-naive sites, limited
technology, lack of trained staff.

Historical mistrust of the
medical system, cultural
and language barriers.

Multipronged approach needed to address the barriers

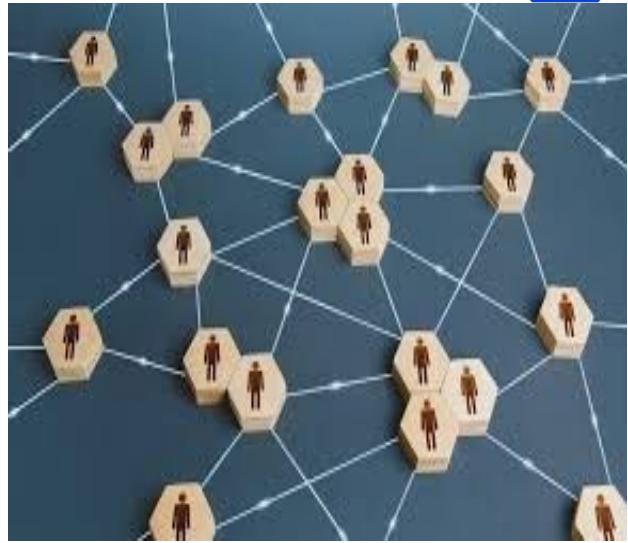


Why Decentralization Matters

Roche

Patients face barriers in traditional trials

- Travel distance, time off work, caregiver burden
- Limited trial sites concentrated in academic centers
- Underrepresentation of diverse populations



Decentralization enables

- Participation closer to home (telehealth, home health, retail clinics)
- Real-world diversity of patients and data
- Increased trust when care is delivered in familiar settings

Sponsor Challenges

What keeps decentralization from scaling?



Regulatory variability

Inconsistent acceptance across regions, unclear guidance



Technology inequity

Broadband, devices, digital literacy not evenly distributed



Site readiness gaps

Community and FQHC sites lack infrastructure for research



Data quality & interoperability

Need to ensure decentralized data meet GCP standards



Trial awareness & trust

Providers and patients often don't see trials as a care option

Opportunities for Sponsors

New Models for Engagement & Delivery



Hybrid trial models: Patients choose which visits are remote vs in-person



Retail & pharmacy partnerships: Local access to labs, vaccines, and basic procedures



Mobile health & home visits: In-home assessments and direct-to-patient medication delivery



Digital tools: Wearables, ePROs, and AI-enabled monitoring for continuous data capture



Equity supports: Assistance for internet, childcare, and transportation costs

No One Can Do This Alone

A Collaborative Ecosystem for Clinical Trials

Successful Decentralized Clinical Trials

Government & Regulators:
Create harmonized DCT frameworks, pragmatic guidance

Academic Centers & Community Sites:
Extend trial capacity into real-world care settings



Advocacy & Patient Groups
Drive awareness of trials as care options



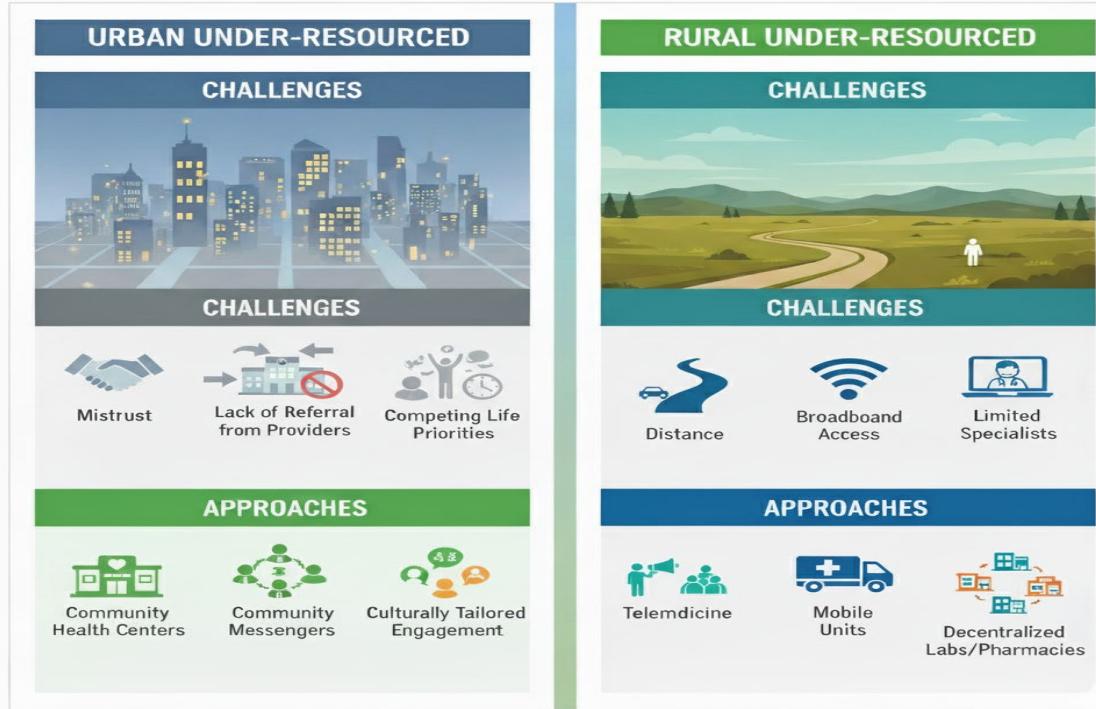
Technology Partners
Provide platforms, home health, and secure data systems



Payers & Health Systems
Integrate trials into standard of care pathways

Public-Private Partnerships

UnderResourced ≠ Always Rural



Different contexts, different solutions

Case Examples



CALL to ACTION: A New Vision for Research



Join Us in Shaping the Future of Inclusive Research



TOGETHER

we can**make** clinical trials

Accessible Equitable Patientcentered

Doing now what patients need next