

Common Roadblocks to Clinical and Translational Science

Roadblock Category	Specific Roadblock
Infrastructure	<ul style="list-style-type: none"> ○ Research cost and lack of funding ○ Lack of national coordination and support for clinical research based on national priorities ○ Mismatches in priorities and incentives among industry sponsors, researchers, clinical care providers, and patients ○ Insufficient national regulatory infrastructure that would allow for accelerated review/approval ○ Lack of communication, coordination, and connection between clinical care and research enterprises ○ Limited multi-institutional clinical trial networks ○ Lacking digital and information technology infrastructure to facilitate trials ○ Inadequate access, transparency, and interoperability of data across clinical care and research
Workforce	<ul style="list-style-type: none"> ○ Lack of qualified C/T investigators (and team members) ○ Limited education/training, mentoring (scientific and cultural) for workforce ○ Lack of education on translational science ○ Impractical academic reward system and career disincentives ○ Researchers compete against each other (poor coordination and limited incentives for collaboration)
Research Management	<ul style="list-style-type: none"> ○ Organizational silos and increasing administrative burden ○ Insufficient project management at all levels of research administration ○ Lack of incentives/credit for team science ○ Limited resources for intellectual property management
Research Methodologies	<ul style="list-style-type: none"> ○ Inefficient methodologies in preclinical development ○ Insufficient use of pleiotropy and promiscuity in therapeutic development ○ Inefficient clinical study designs; underuse of registries and natural history studies, biomarker qualification, pharmacoepidemiologic studies, comparative effectiveness trials, adaptive clinical trial designs ○ Limited implementation of evidence-based practices
Clinical Trial Operational Inefficiencies	<ul style="list-style-type: none"> ○ Lack of innovation solutions to the primary causes of clinical trial delay and cost including: <ul style="list-style-type: none"> ○ multisite institutional review board (IRB) review and contracting, ○ site and investigator qualification, ○ recruitment and retention (particularly of URM) ○ surge capacity, ○ adequacy and timeliness of results reporting. ○ Lack of sufficient community and stakeholder engagement and outreach to underrepresented groups ○ Lack of robust strategies for ongoing patient and community collaborations that are demonstrated to shorten the time and/or improve efficiency