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Single Day Event

Stitching Together Point Solutions for Achieving End-to-end Efficiencies and Standardization: Lessons from Key Stakeholder Interviews

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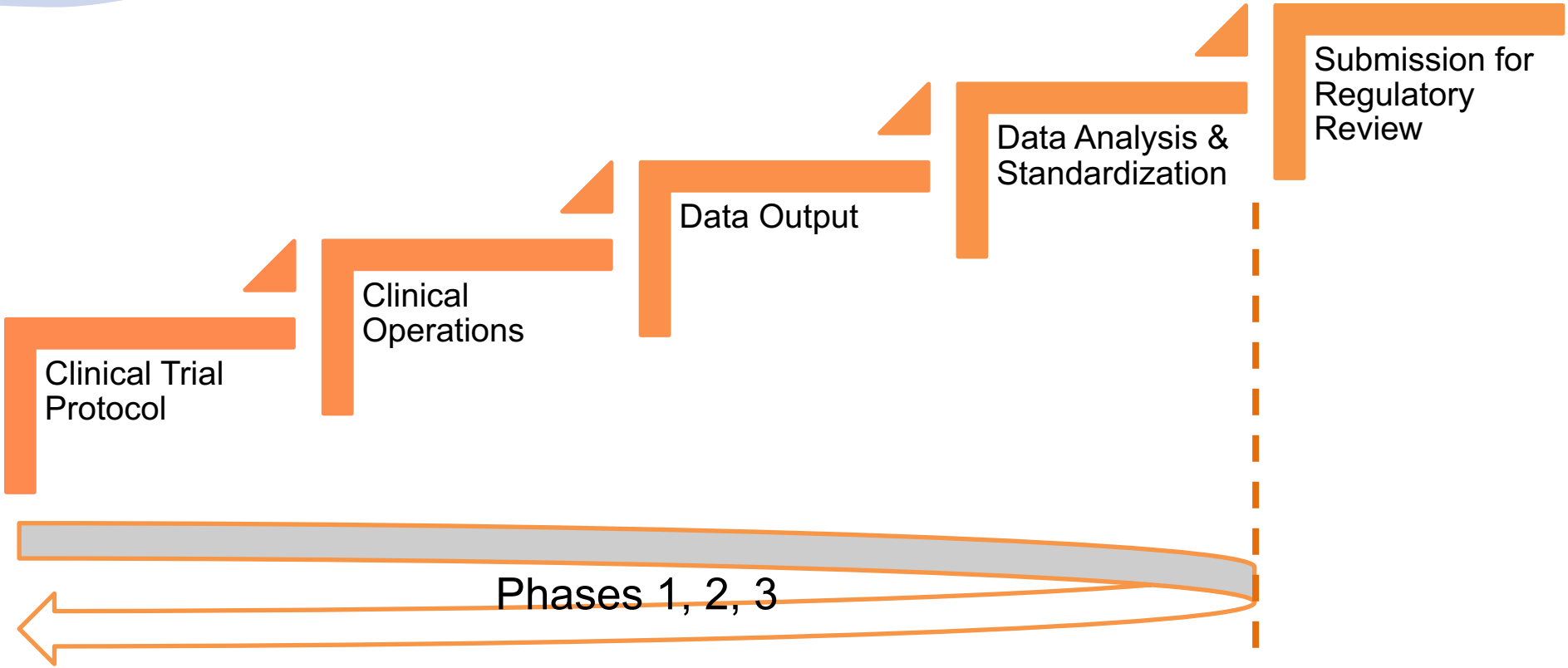
Additional Affiliations and Disclaimers

- Perspectives are Personal
- Rare Dad, Data Scientist, Social Entrepreneur
- Founder and Chairman, Indo US Organization for Rare Diseases
- Founder and CEO, Jeeva eClinical Cloud
- Affiliate Faculty, George Mason University, Fairfax, VA
- Board Member, Greater Gift
- Advisory Board, Synergy BIS
- Working Committee Member, RDDC

A Clinical Trial



Inefficiencies in Clinical Trials

Cost Sponsors Significant Delays

1. Protocol Design
2. Site Selection
3. Approvals Prior to Study
4. Configure Study
5. Patient Recruitment
6. Clinician Assessment
7. Follow Up Visits
8. Patient Reported Outcomes
9. Return Results to Patients
10. Regulatory Review

CDISC Data

7-9 years Versus

5-6 years & up to **80%** cost savings

What Keeps a ClinOps Up At Night?

Cost

Patient Recruitment & Retention

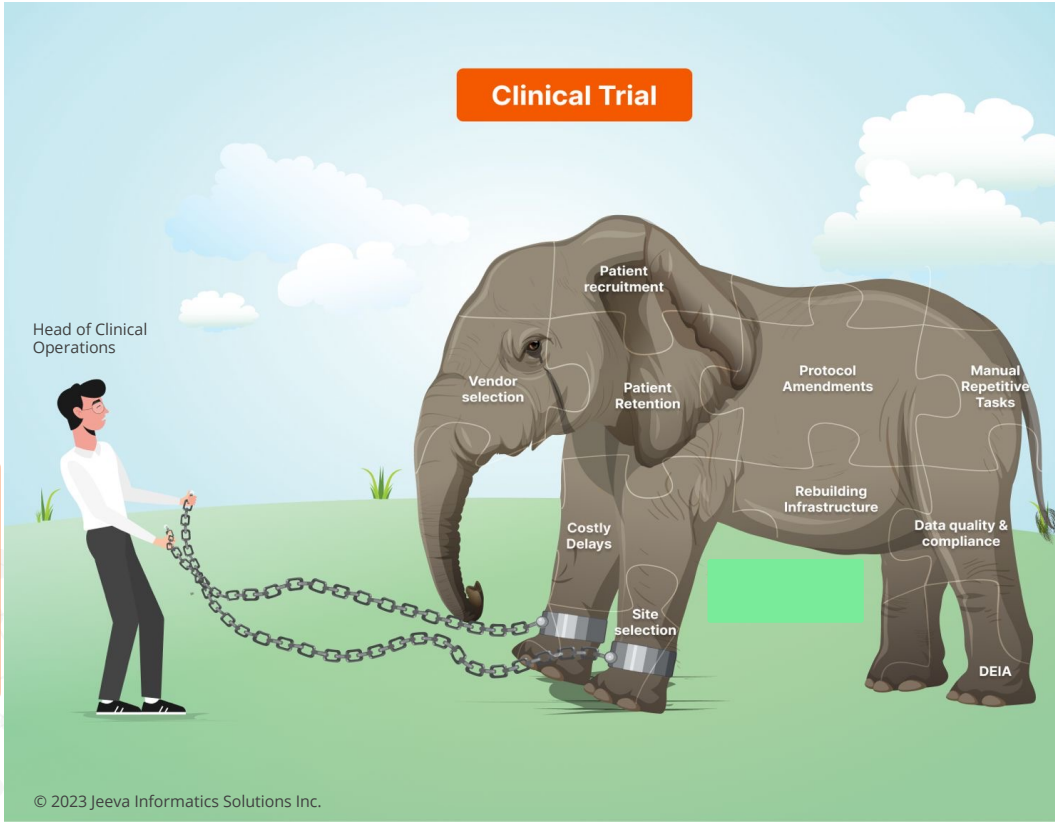
Managing Protocol Complexity & Amendments

Vendor Management

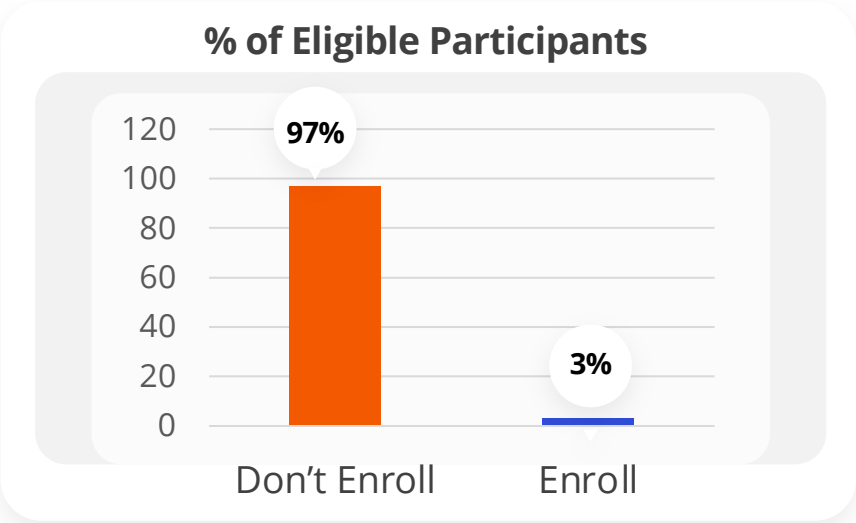
CRO, Software Tools, Validation and Training

Manual Repetitive Tasks and Errors

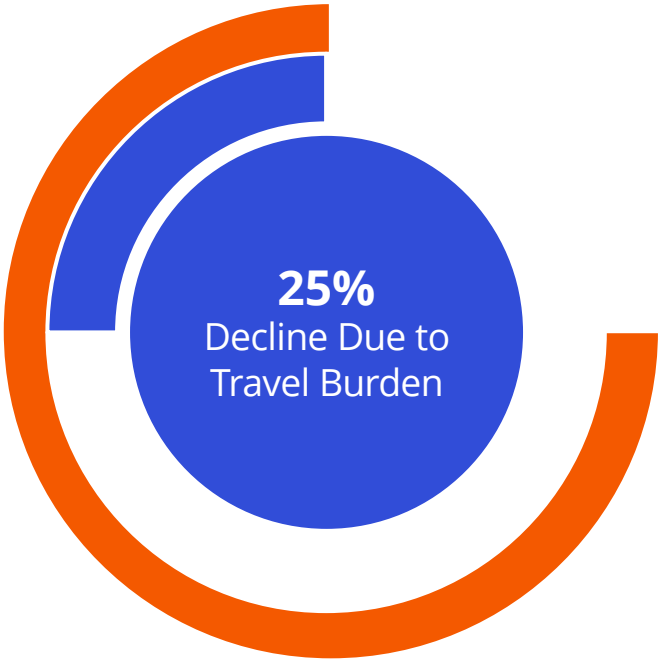
Diversity



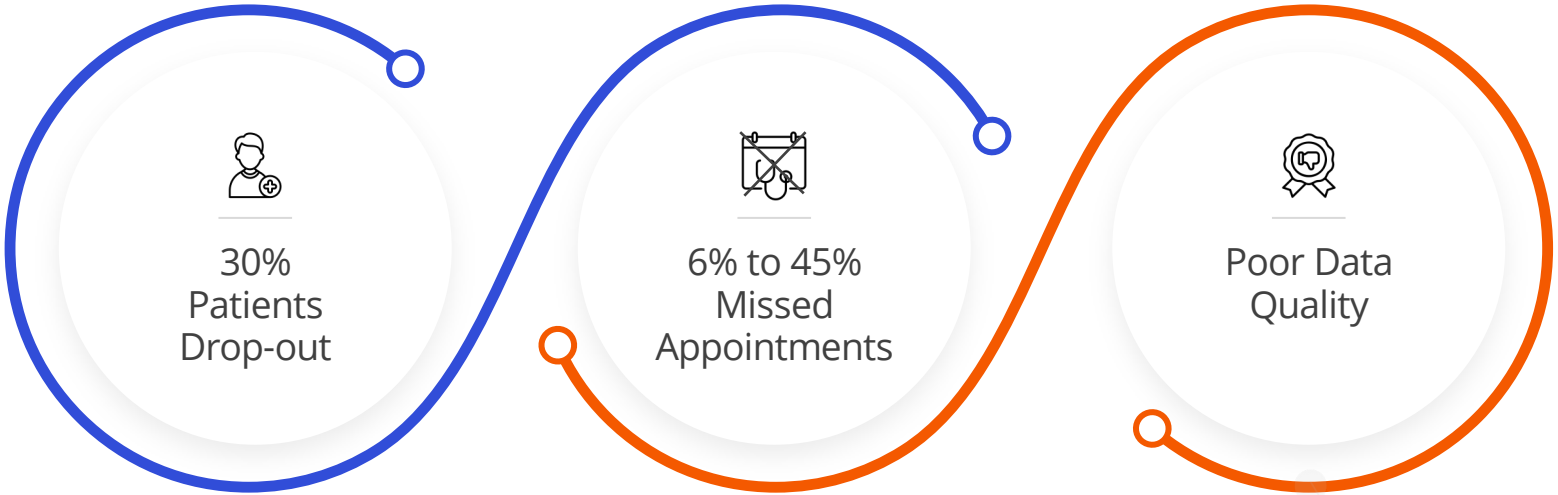
Problem: Patient Enrollment



Addressable Problem: Travel Burden



30% of Clinical Trials Terminate Due to Poor Enrollment



https://link.springer.com/article/10.1007/s11606-021-06935-x#:~:text=In%20a%20systematic%20review%20of,ranged%20from%206%20to%2045%25.

Patient Recruitment & Retention

Patient Touchpoints

Difficult to locate the patients and mapping them to investigator sites

Screen failures - identifying the right patients is cumbersome

Logistical issue - tough for patients to travel, get off work, or lose income to travel

PPT* Strategies

Workflows generating inbound traffic to specific sites or central recruitment centers from various channels such as social media, emails, or SMS

Automated or semi-automated participant outreach and screening workflows

Accelerated nurse concierge screening patients via phone calls or questionnaires

Complement sites own medical records with online patient identification and screening

PPT*: People, Process, Technology

3 Dimensions of Protocol Complexity

Protocol

- Multiple Treatment Arms
- Dynamic Visit Schedules
- Personalized Medicine
- Single- or double-blind
- Dynamic Cohorts
- Multiple Disease Types

Operations

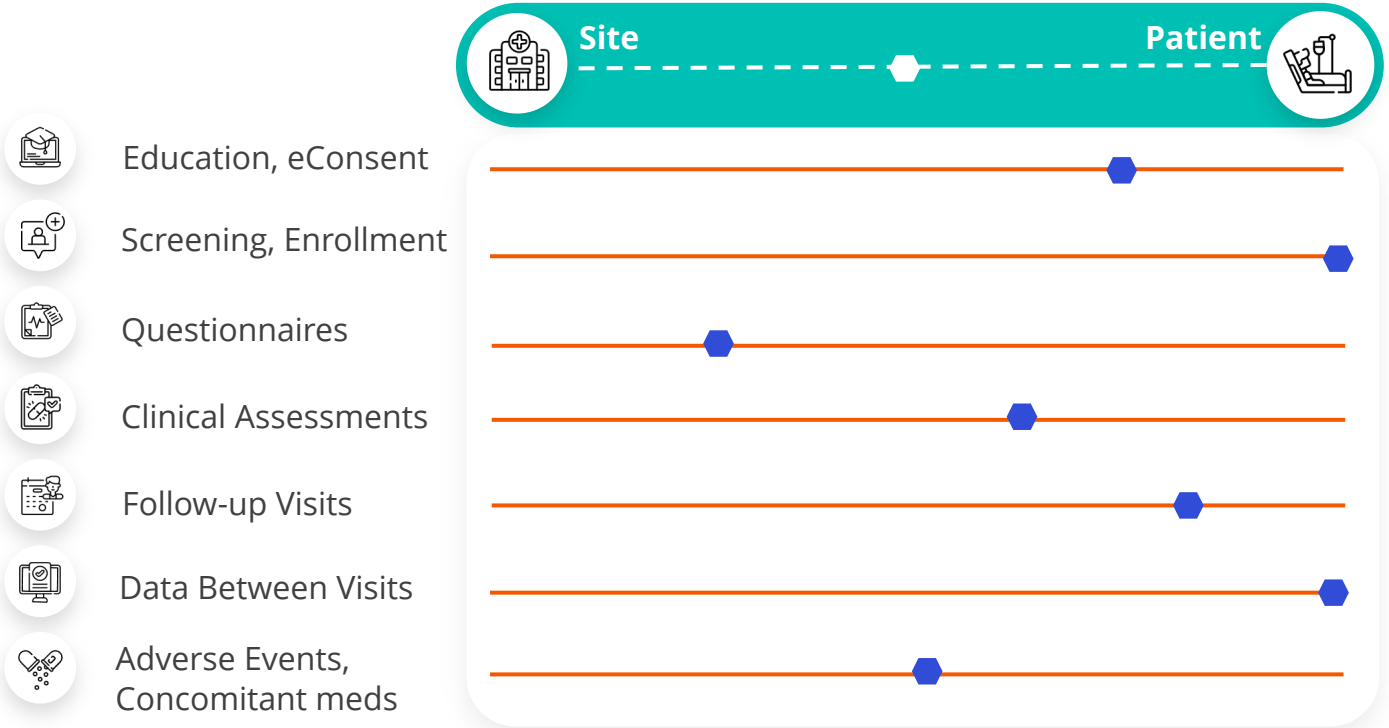
- Direct to Patient
- Decentralized or Hybrid
- CDx
- Long-Term Duration
- Multi-Site Visit Option

Unexpected Change

- New Treatment Arm, Schedule Change
- Protocol Amendments
- New Country Added
- Pandemic, War, Volcano

https://www.drugdiscoverytrends.com/defining-complexity-a-framework-to-identify-complex-clinical-trials-and-set-them-up-for-success/

Protocol Complexity: Traditional, Hybrid, or Decentralized



Centralized schedule of visits that configures most protocols

Manual Versus Automation

Manual Repetitive Tasks

Individual Informed Consent, Patient Screening, Education

Study Configuration and Form Libraries for eCRFs, eCOA, ePRO

Data Standards, SDTM, CDASH, MedDRA, WHODrugDB, Data coding

Patient Engagement, Reminders, Notifications, SMS, Email, Tele-, Video-

Automation

Remote eConsent
Automated Screening Workflows
Patient Education Content Workflows

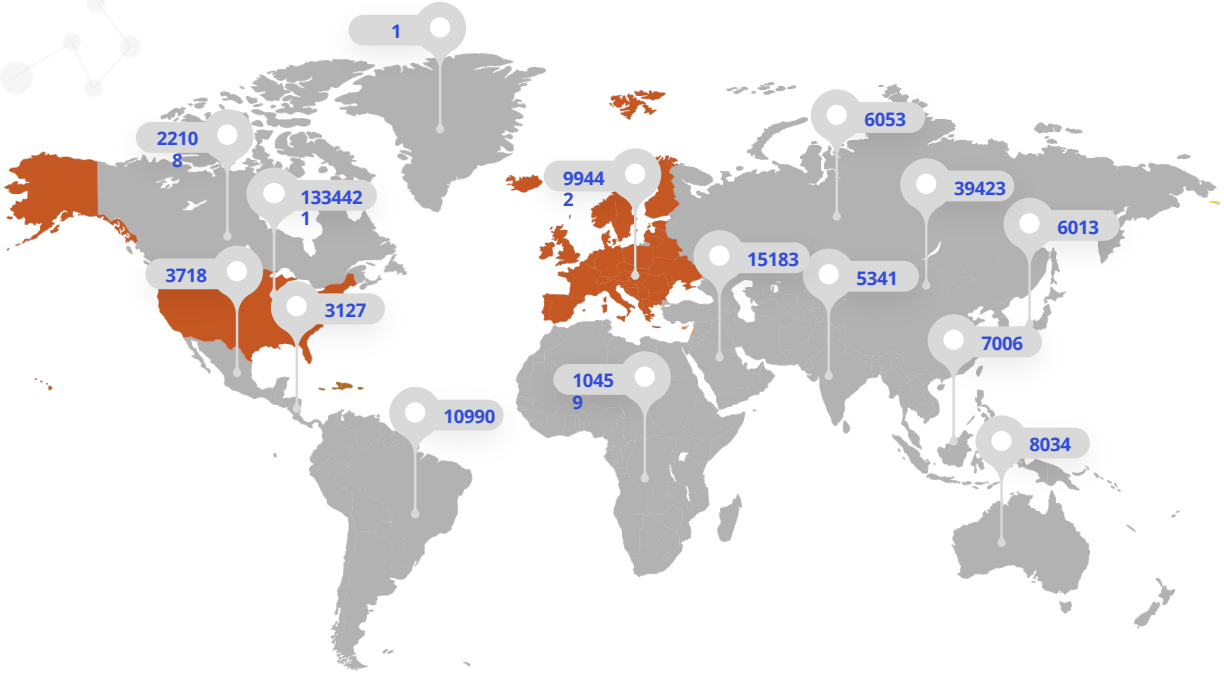
Duplicate Study
Duplicate a Form
Borrow Form from Library

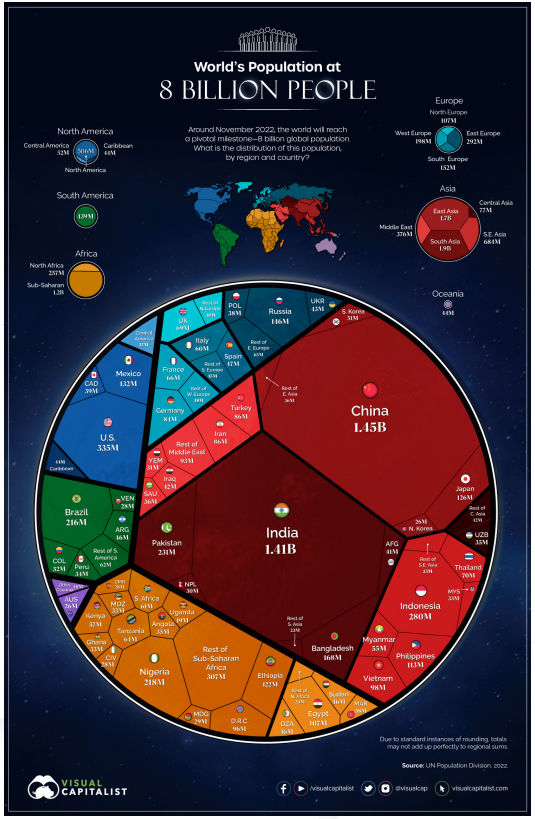
Data mapping to variables
No Surprise Data Exports
Reporting Options

Hyper-Personalized Communications
Visits or Modules or Appointments
Only to those who need them

Lack of Diversity in Clinical Trials

Underrepresentation of Age, Gender, Race, Ethnicities, Cultures, Geographic, and Genetic diversity





Source: https://clinicaltrials.gov

What Does it Take to Achieve DEIA in Clinical Trials?

Regulatory Policies, Guidelines, and Mandates

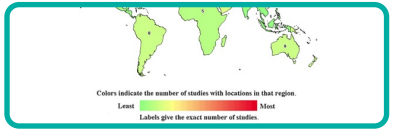
- Legislative Advocacy. IRA, 21st Century Cures, Orphan Drug Act, Amendments
- Executive Branches Guidelines and Frameworks. DCT guidelines and REDP guidelines
- International Guidelines/Communities (ICH, Belmont report, Helsinki declaration, SDTM, CDISC, CDASH, PHUSE)

Commitment Among All Stakeholders with Shared Goal

- Walk the talk. Not just lip service
- Metrics for Each Stakeholder Aligned with IDEA goals

Inclusive Digital and Data Platforms

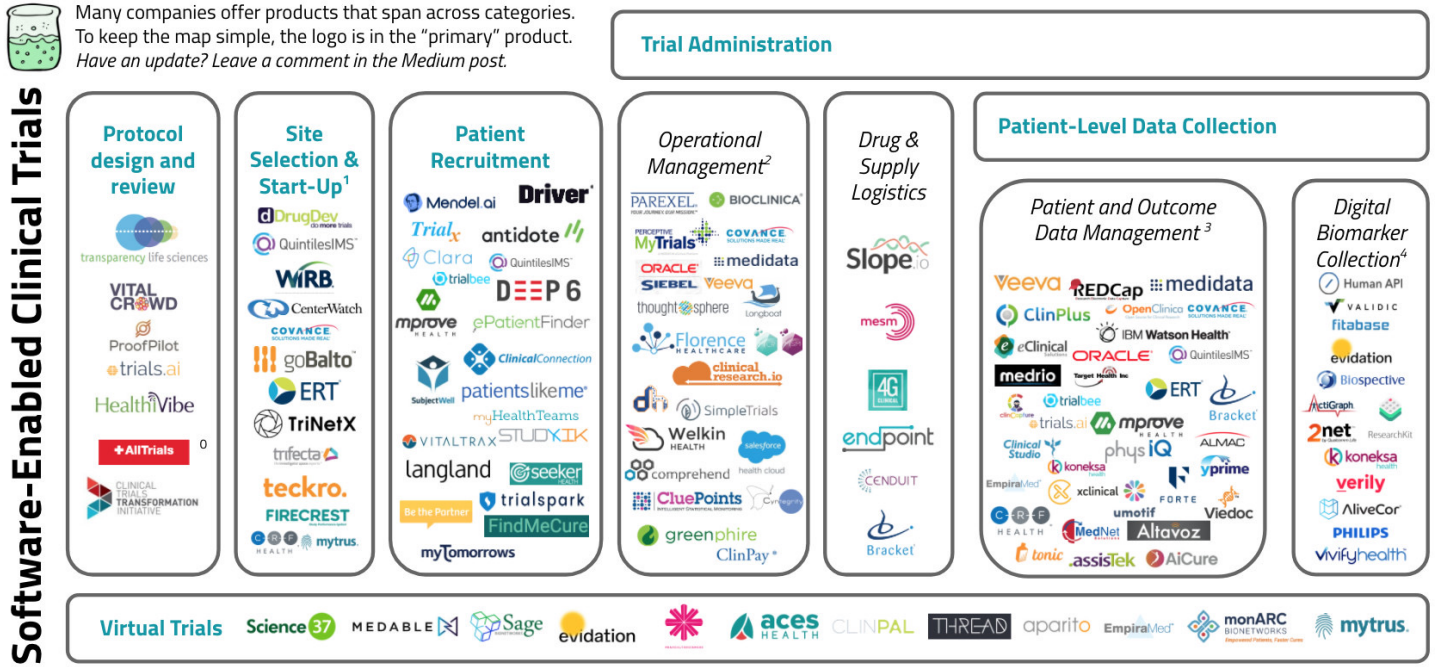
- Demographic data for all diversity parameters
- Prevalence, Incidence, Epidemiology Data for Diseases for all populations
- Digital Platforms that support languages, cultures, religions



Global Thinking and Cross-Border Collaboration

Next generation training and education programs for cultural competency for all stakeholders

Stitching 30+ Vendors, Qualification, & Compliance



0 Unlike the other for-profit ventures on this map, CTTI is a Public-Private partnership & AllTrials is a registered charity
1 Includes startup tools like eConsent and site training
2 Includes clinical trial management systems, risk-based monitoring, site monitoring, payment automation
3 Includes EDC (electronic data capture), eCOA (Electronic Clinical Outcomes Assessment), and ePRO (electronic Patient Reported Outcome)
4 Includes clinically-validated sensors

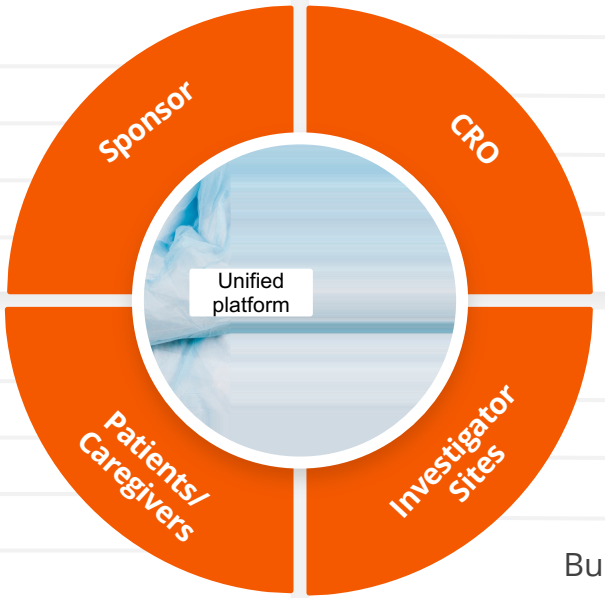
2017 by @AndreaCoravos

Cost Considerations for Sponsors and CROs

- Number of Users & Duration
- Direct vs Indirect Costs
- 24x7 vs 8x5 Support
- LPLV timeline can cause budget overruns
- Vendor qualification, validation, management
- Fixed or T&M?

Enable Stakeholder Collaboration

- Study startup timelines
- Risk of failure
- Quality & compliance
- Data security & privacy



- Study management
- Statistical Programming
- Data Management
- Site monitoring
- Vendor relationships

- Results return
- User Experience
- Burden
- Access & support
- Safety & AEs

- Patient safety, AEs
- IRB/Ethics compliance
- Audit readiness
- Burden of 10-30 logins per trial

Why Now?

Tailwinds of Pandemic Driven Decentralization

Willingness of Life Science Industry to Adopt Digital Tech

New FDA Guidance on Patient Diversity, Equity, Inclusion, Access

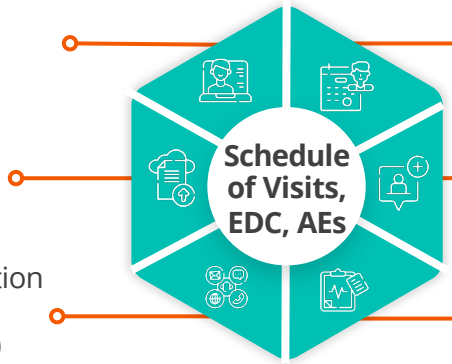
Unified EDC+CTMS+DCT Platform

Status Quo
Piecing together Point Solutions

TeleVisits
VideoVisits

Clinicians or
Patients Upload
Lab Reports

Communication
(SMS, email,
audio, video)



eConsent

Remote
Screening,
Enrollment

ePRO
eCOA

Centralized, Study-Specific

Patient engagement portal

Centralized schedule of visits

Manage protocol amendments

Re-usable infrastructure
- No IT setup cost

USPTO Patent Pending

Put ClinOps In the Drivers Seat!

Cost

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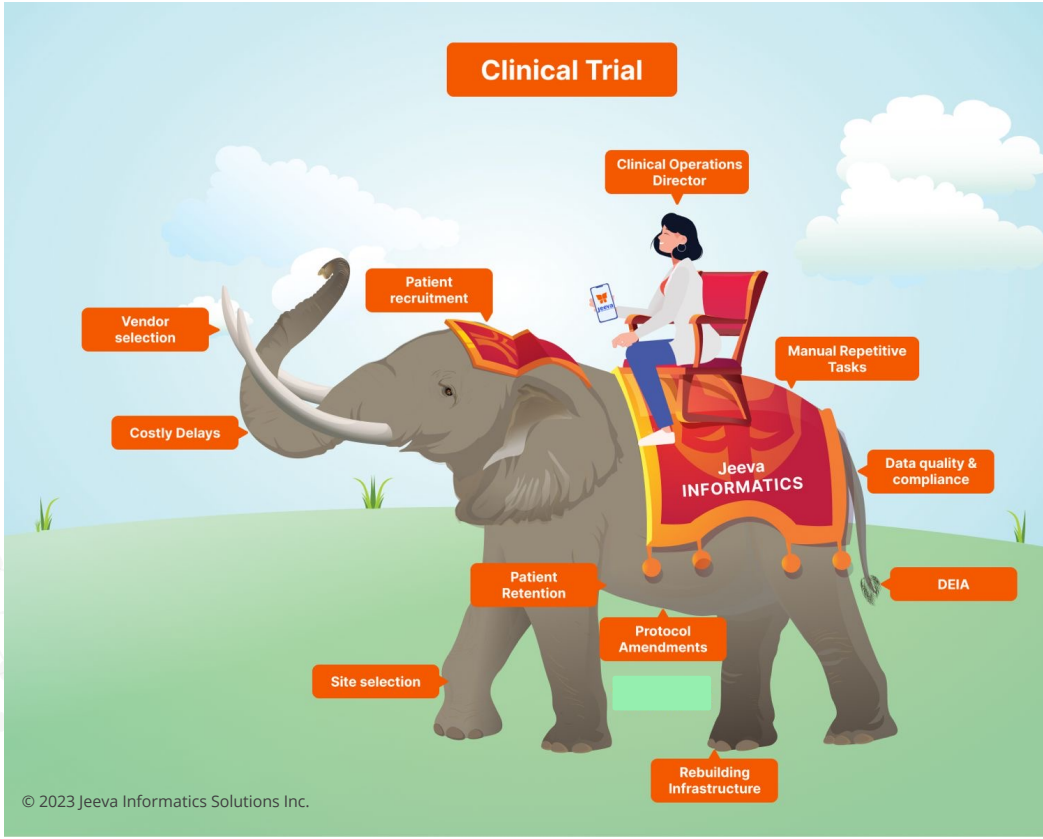
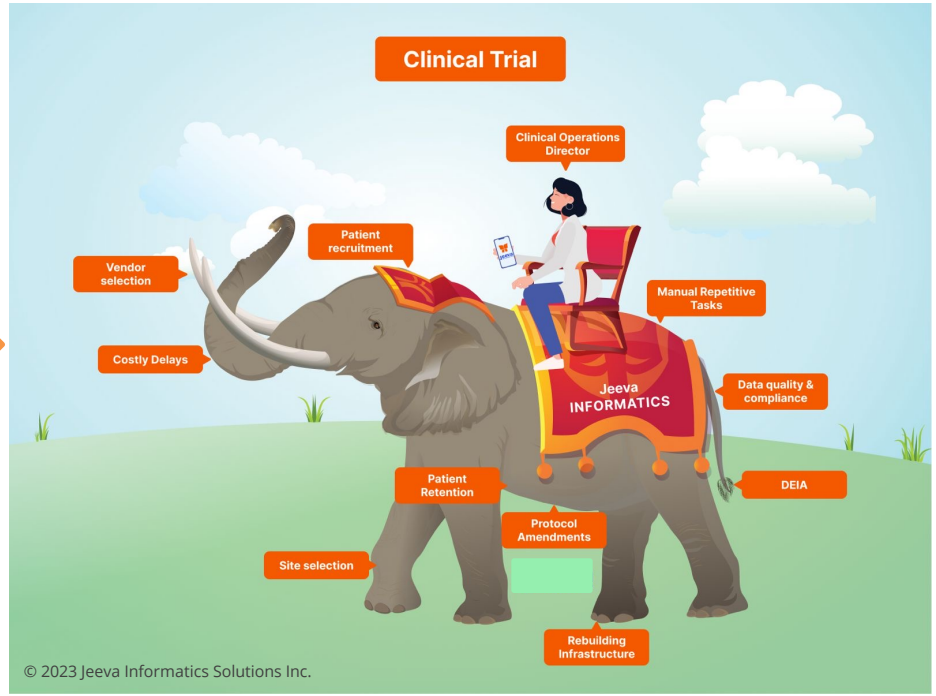


The Next Gen Clinical Trial:
Human-, Patient-, Data-, or Site- Centric?

Clinical Trial Protocol



MedDRA, WHODrug, SDTM Standardized Data Ready for Analysis

CDASH eCTD Ready for Submission