Special Report

Emerging Trends in Clinical Trial Landscape

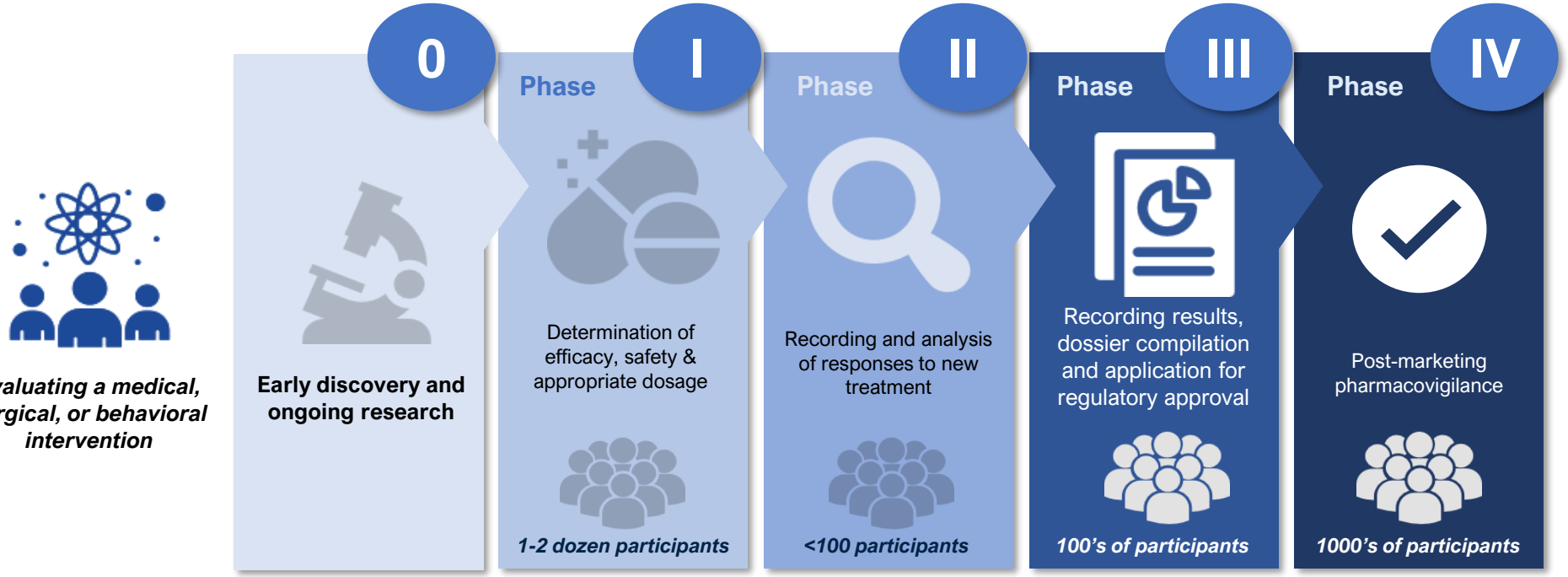
Post COVID-19 Innovations and Disruptions in Clinical Trials

aranca

March 2023

Clinical Trials – An Overview

Traditionally clinical trial design includes five stages - from preclinical Phase 0 to Phase IV regulatory approval for commercial use



Application Areas

- Compare extent of effectiveness and safety profile versus standard treatment
- Test ways to detect a disease early, before symptoms arise
- Access to novel treatment options, before commercialization
- Study the role of caregivers or support groups

Source: *Secondary Research, Industry Analysis*

Challenges to traditional clinical trial process during the COVID-19 pandemic

During the pandemic, trials faced disruptions due to lockdowns, site closures, export bans and patients' reluctance to participate

Impact on Facilities

Moving of non-clinical staff off-site

Diversion of research staff to supportCOVID-19 studies.

Shut down of on-site monitoring facilities

The life sciences industry saw the disruption of ~80% of non-COVID-19 trials

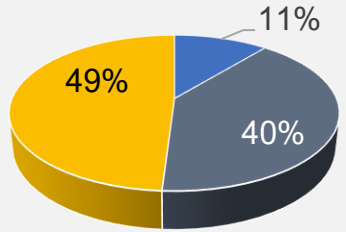
Suspension of patient enrollments for trials

As of Jan,'21, there were >2000 trials that has been stopped due to COVID-19 restrictions

Impact on Patients

Global lockdowns hampered onsite patient participation, thus delaying study timelines

Report on global clinical trials



Added challenge of safeguarding patient's health for trials that were ongoing (e.g.: Oncology studies)

Patients' reluctance to participate, over fear of infection caused slow enrollments and increased dropout rates

Impact on clinical trial supplies

Export bans in the initial months of the pandemic caused cancellation of orders for comparator drugs for many studies.

Governments broadened list of critical medicines that needed to be kept in stock, making procurement harder for trials

Several anti-viral drugs became candidates for COVID-19 treatment, thereby restricting their use in research studies

For companies that were able to secure comparator drugs, they had more inventory, than patients who enrolled for the trials.

Due to finite shelf life of these comparators, the issues of storage, waste and lost revenue became a grave reality

Source: *Secondary Research, Industry Analysis*

Changes and innovations in clinical trial approaches

Ensuring patient safety while carrying out trials amidst the pandemic was challenging – leading to increased adoption of remote technologies and services

Telemedicine was implemented for routine follow ups, to identify adverse events in Phase 1 studies.

eConsent was perceived to be easiest to implement, to communicate with patients through video explanation, quizzes etc.

ePRO adoption increased, and research organizations allowed patients to use own devices to report outcomes.

Home Healthcare helped researchers ensure that patients who were unable or unwilling to travel, received the medications and could provide samples when needed.

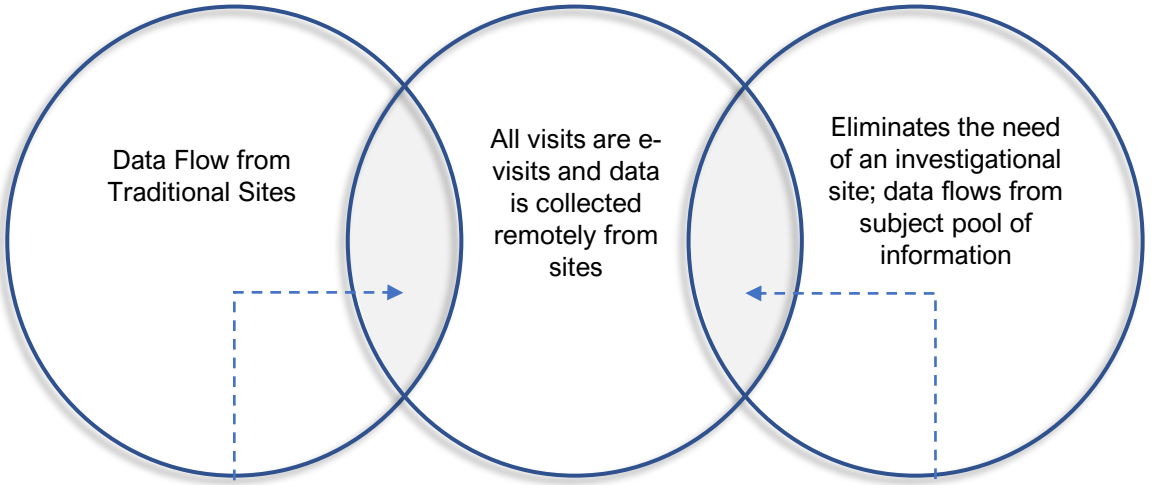
Decentralization of lab work allowed participants to do blood work at local labs, with investigators providing copay cards to cover the cost of the same, in some cases, which was effective for oncology/ rare-disease patients.

Direct to patient drug delivery was perceived to be low-risk for patient centric trials with oral agents having safer toxicity profiles

Source: *Secondary Research, Industry Analysis*

Acceleration of Decentralized trials (DCTs)

Emergence of remote monitoring technologies paved way for organizations to easily conduct decentralized, virtual clinical trials



Hybrid Virtual Trials

Data Flow from Traditional Sites

Partial DCT Trials

May have few predefined sites for data collection, combined with data from subject pool

In a survey by Oracle Health Sciences, ~76% of industry professionals stated that COVID-19 accelerated the implementation of DCT modalities, in their organization

IQVIA

Innovative platforms like ***IQVIA Virtual Trials***, coupled with smart technology (Smartphones, wearables, AI/ML, cloud computing etc.), is helping clinicians and pharma organizations in adopting and conducting DCTs or hybrid trials

DTRA DECENTRALIZED TRIALS & RESEARCH ALLIANCE

The DTRA is working with industry stakeholders, towards a common goal of making trials accessible, by expanding policies, applied research and investing in tech. innovations that support decentralized trials.

Interoperability plays a critical role for seamless data flow, from patients, to the site and ultimately to investigators, using software with Open APIs. This integrated technology helps eliminate redundant data and speed study timelines, while expanding inclusion of patient populations and retention in study activities.

Source: *Secondary Research, Industry Analysis*

aranca

Regulatory changes favouring adoption of novel technologies for DCT's

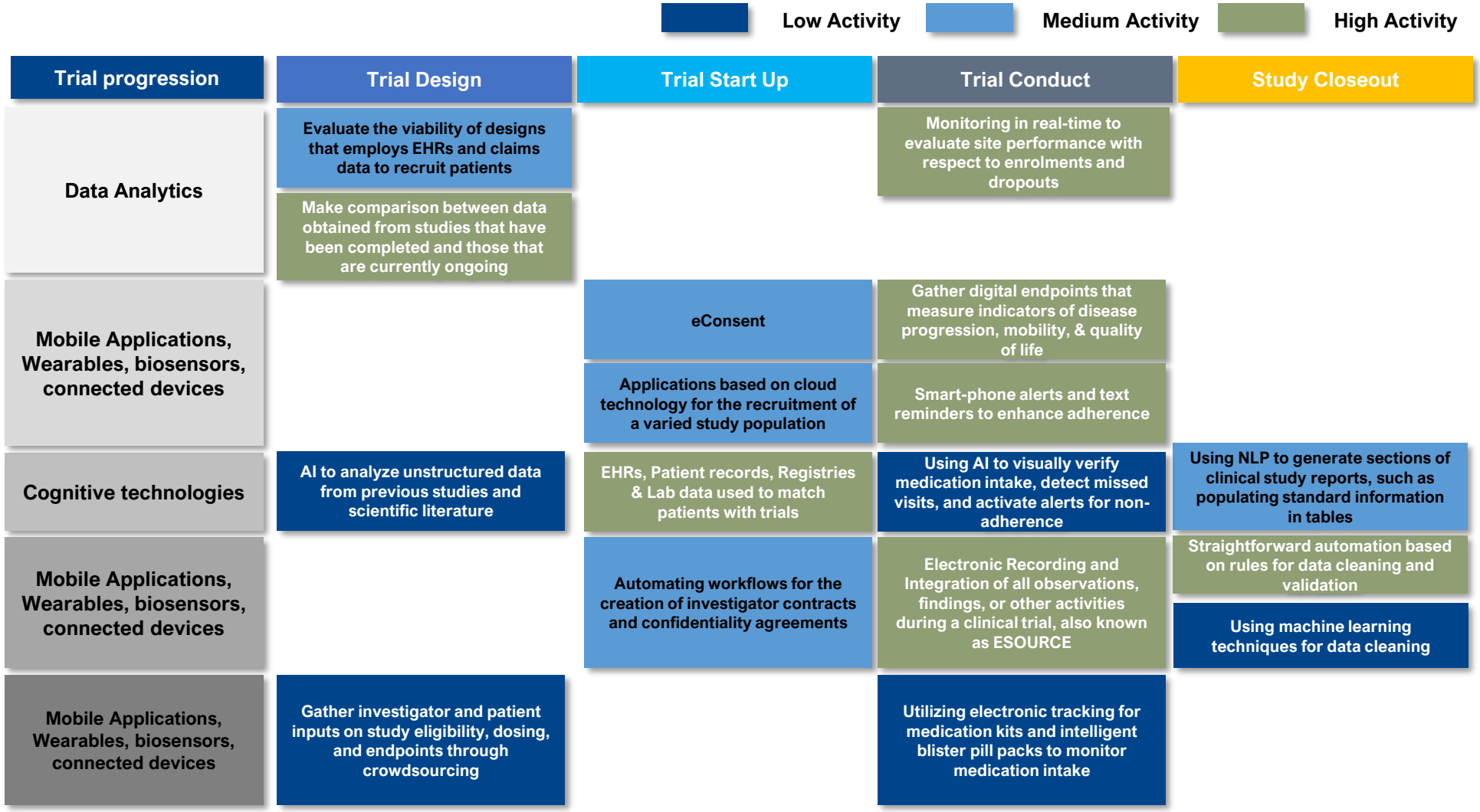
Global regulatory agencies have amended existing protocols to accommodate use of novel trial designs while ensuring patient safety

Measures	FDA	EMA	PMDA
Telemedicine (study visits via phone/video)	✓	✓	✓
Verbal Informed Consent	✓	✓	✓
Delivering Medicinal Products for subjects by delegated study nurse	✓	✓	✗
Delivering Medicinal Products for subjects by third party logistics	✓	✓	✗
Home-based medical care	✓	✓	✓
Study visits in another hospital	✗	✗	✓
Receiving medicinal products by subjects' family	✗	✗	✓
Changing the protocol without permission of IRB, if necessary	✓	✓	✗
Remote monitoring	✓	✓	✗
Remote Inspections	✓	✓	✓
Electronic Consent (eConsent)	✓	✗	✗

Source: *Secondary Research, Industry Analysis*

Impact of various digital technologies on the future of clinical trials

Technologies like NLP, AI/ML and cloud computing for data analysis, will drive the future of clinical trials



Source: *Regulatory agency websites, Secondary Research, Industry Analysis*

Right from understanding key issues to advising you through the right set of insights and recommendations, we can help in making the best business decisions

Market Opportunity

Innovative Clinical Trial Design and Management

Move from traditional clinical trial designs to patient-centric studies, involving use of novel technologies:

- Deploying Artificial Intelligence in trial design, to analyze unstructured data from previous studies.
- Integrating EHR data for patient recruitment for appropriate trials during design and start-up.
- Using Natural Language Processing (NLP) for writing portions of clinical trial reports.
- Employing smartphones, as digital touchpoints, to capture data on disease progression, treatment efficacy and quality of life, during the trial.

How Can Aranca Help?

- Clinical Trial Market Assessment
- Clinical Benchmarking:
  Analysis of current clinical trial designs in the industry
- Opportunity assessment for incorporation of novel technologies in traditional clinical trial design and development
- Assessment of Regulatory and Infrastructure requirements to set up early-stage trials
- Identify key CRO partners for conducting clinical trials
- Technological opportunity assessment:
  Technology Landscape Assessment | Competitive Intelligence | Partner Identification | Target Assessment

Aranca enables you to leverage emerging opportunities by constantly scouting for assets, identifying market optimization and synergistic prospects, conducting due diligence and asset valuations, and supporting transactions.

500+
Strong team of professionals across multi-disciplinary domains

2500+
Global clients

120+
Sectors and sub-sectors researched by our analysts

80+
Countries where we have delivered projects

ABOUT ARANCA

Growth Advisory
CXOs in Strategy, SBUs, Sales, Marketing, CI/MI, Innovation

Valuation & Financial Advisory
CFOs in Start-ups, PE/VC Firms, Corporate M&A Teams, Mid-market Companies

Technology | IP Research & Advisory
R&D, Tech Scouting, Open Innovation, IP Teams, Product Development

Investment Research & Analytics
Brokerage, Hedge Funds, IRPs, I-Banks, AMCs, Investor Relations

Connect with our Team

Vibin Theril

Associate Vice President – Growth Advisory

+91 9819350761

vibin.theril@aranca.com

Kartikeya Rao

Senior Consultant – Growth Advisory

+91 9022654622

kartikeya.rao@aranca.com

For more details: *www.aranca.com* | *https://www.linkedin.com/company/aranca* | *https://www.aranca.com/knowledge-library*

Decide Fearlessly

From startups to the Fortune 500, private equity and global financial firms, Aranca is the trusted research and advisory partner for over 2500 companies

www.aranca.com