

Emerging from the Pandemic: Finding a Proper Balance (MASS East)

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Problem Statement: Clinical Trials + Medical Affairs Suffered

- Trial Patient Participation Reluctance
- PI move to Covid Clinics
- Trial Hold/Cancelation
- Drug Development Delays
- HCP Engagement Dwindled
- Regulatory Recalcitrance
- Big Pharma better equipped/Small Biotech struggled
- Cost of Clinical Trials higher (TMF Report 2021)

Marrying In-person Trials with Decentralized Clinical Trials: Finding that 'Goldilocks Zone'



Activities for DCT Conduct

- Most CT'S won't be entirely virtual
- Will use DCT elements based on Suitability of Endpoints
- Site Activation*
 1. Remote and Central Site Monitoring
 2. Site Preactivation and Remote Activation
 3. Digitized Investigator Engagement and Payment
- Patient Enrolment
 1. Patient Online ID and Recruitment
 2. Digital Trial Marketing and Patient activation
- Trial Conduct
 1. Trail Decentralization: Homes/Pop-up Clinics/Pharmacies
 2. In-home Assessments/Phlebotomy/ Infusions
 3. D2P Clinical Supply

Activities for DCT Conduct

- Digital Patient Engagement

1. Telemedicine
2. Remote Pt Monitoring, incl. Efficacy
3. E- Clinical Outcome Assessment and e-PRO
4. E-Consent

Hybrid Nutshell:

1. Touchpoints Closer to Patient (Remote Vitals, Apps, Home)
2. Screenings/MRI's/Complexity: Traditional Site Visit
3. Smart Design: PCP's Virtual, Mobile Clinics
whenever possible.

Digital Innovations

- Patient-Centric: Informed Collaborators
- Remote Patient Monitoring
- Wearables, mHealth, ePRO, Sensors, Telehealth
- Physiological Data, Drug mechanics, pK
- Mobile Med. Management
- mHealth: Medical Imaging
- Ex. FDA Appr. Butterfly IQ Phone Ultrasound
- Speeds up CT's in Smaller Practices.
- All Dig. Innovations Speed All Trials

Amping up Technology, including AI/ML stratification, to accelerate 'Go-to -Market' Strategies

- AI/ML ID's + validates D. Targets
- Crafting CP+ CSD(Ex: Trials.ai)--1st draft CP by Machine?
- Drug Discovery: Design, Repurpose (Intromune?)
- Aggregate + Analyze EHR Biodata
- Patient Recruitment (No.1 Trial issue- AI+ML+ Annotated NLP)
- Open-Source NLP Ex: Criteria2Query (I/E)
- Pts--> DQuest--> ClinicalTrials.gov--> Plain English
- AI/ML: Medical Imaging

RCT Dinosaurs?

- Firms Pt. Self-Trial Search (Ex: Antidote)
- Deep6AI Cedars-Sinai Heart LA (16 folks/1 hr vs. 2/6 mo.)
- CT Diversity (Democratize Access)
- Evaluating AI: Shared Framework Key (Silos)
- Buzzy, Bit Hyperbolic—Clinical Validation Key
- Demonstrate Reproducibility
- Build Regulator Confidence
- Post Drug Approval--EHR at Scale shows Pt. Response
- Obviate RCT's Holy Grail--Cohort Simulation

Sustaining Biotech Investor Interest in a post-pandemic paradigm

- Clinical trial failures + Regulatory setbacks
- Drug Pricing concerns
- Funders Unwinding Speculative Bets
- 2022 Forecast: M&A Uptick (Strong B/S, Patent Expirations, Depressed Smid-cap Vals.)
- Biotech Visibility High post Pandemic
- Covid Vaccines/Monoclonals/Therapeutics still Buzzy.
- CGT Space heating up (Funders+ FDA Amenability + 'Cure' Lure)
-  2021 Early-Stage Co. Private Investment → Future IPO's.
- Favorable Base Val. →  Public Market Investments

Investor Blue-Sky Outlook

- New Drug Targets (even few new Antibiotics)
- Innovation in Design, Manufacturing.
- Advanced CGT Delivery
- Expansion into new diseases (particularly Onco, Neuro, and Rare disease)--> Investor Enthusiasm for the Industry in 2022.

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Thank You!

Questions?

