Data Science for Life Science

Digital Clinical Trials
Leveraging AI, Mobile, Analytics, Cloud, Sensors & Connected Devices

Avik Pal, CEO
Avik Pal

CEO, CliniOps
Board Member, iKure
FocusFrame (acquired by SAP)
Euclid Inc. (acquired by Persistent Technologies)

MBA, USF; B. Tech, IIT

Speaker: DIA Conference, Scope Summit, FDA Innovation Summit

Delegate, US Department of State,
Global Entrepreneurship Summit, 2017
Delegate Lead: Ivanka Trump

Top 50 Indian Entrepreneurs in the US, 2017
The Technology Headlines
Agenda

• Data Science for Life Science
• Solution
• Value Proposition
• Use Case
• Impact
• Traction & Recognition
Clinical Operations

Clinical Data Management

Biostatistics & Regulatory

Legacy EDC Systems

Real-time data science

Applicable on Real-time data
The Value Proposition: eClinical Workflow Optimization

**eSource Advantage**

- **Electronic Source**
  - Digital Tablets

- **Data Collection**
  - From Patient Home

- **Central Monitoring**
  - (rSDV)
  - Minimal Travel

- **Also in**
  - Remote areas

- **Applied on**
  - Realtime data

**Data Collection**
- **Telemedicine**
- **Data Monitoring**
- **Patient Diversity**
- **Data Science**

**Traditional EDC Workflow**
- **Paper CRF’s**
  - Manual Transcription

- **Data Collection**
  - At sites

- **Significant Travel**
  - Extensive SDV

- **Only in**
  - High end hospitals

- **Only in**
  - Retrospective data

High data quality,
Less time & money

Low data quality,
Significant time & money

Copyright © 2019 CliniOps, Inc.
The Solution: CliniOps™ App Suite

- Users
- Investigators
- Sites
- Lab
- Security
- Study Admin
- Access Control

CliniOps eSource

Offline | Mobile Digital | Compliant

CliniOps EDC
CliniOps ePRO
CliniOps eICF
CliniOps Coder
CliniOps IRT
CliniOps CTMS

Foundation → Source → App Suite → Visualization

- Reports
- Dashboards
- Analytics
- Trends
- Decision Support

Copyright © 2019 CliniOps, Inc.
The Solution: CliniOps™ DCT Suite *(Decentralized Clinical Trial)*

- Current Industry Approach: Push Trial Sites ➔ Home
- CliniOps Differentiation: Push Patient Visits ➔ Home
  - Once all patient data can be collected from home, it will eventually be a virtual trial

- CliniOps provides the Technology solution
  - That works ‘Today’ (Current Conditions)
  - And supports ‘Tomorrow’ (Future Proof), with IoT, Smart Devices, Smart Homes
CliniOps: Data Science for Life Science

- **Patient Home**
  - Instant Notification for abnormal patterns
  - Continuous Patient Data
  - Easy, Passive & Clean

- **Trial Site**
  - Integrated Med Devices & Ecosystem applications

- **App Suite**
  - AI / ML

- **Built-In App Suite**
  - EDC
  - ePRO
  - eICF
  - Coding
  - IRT
  - CTMS

- **Sponsor / CRO**
  - Unified Dashboard
  - Single source of truth
CliniOps Impact: Digital Transformation in Real World

2016
Lymphatic Filariasis (LF) Eradication

2017
Global Policy Report Published

2018
Benefits on the ground realized

Neglected no more
A massive success
Kenyan Ministry of Health
The Traction: Global Adoption

Customers
- Pharmaceutical
- Biotech
- Med Device
- Academia
- Foundation

Disease Areas
- Lymphatic Filariasis
- Kidney disease (AKD)
- CNS/Psychiatry
- Diabetes
- Hepatitis
- Asthma
- HIV / AIDS
- Malaria

Sites currently in operation

Sites starting soon

75,000+ PATIENTS
500,000+ VISITS
20+ COUNTRIES
5+ Million DATA POINTS
10+ LANGUAGES
FDA 21 CFR 11 COMPLIANT
ISO CERTIFIED
GDPR READY

ISO CERTIFIED

GDPR READY