## Making Virtual Trials a Reality

## Virtual Trials Bring Speed Back to Clinical Trials



## COVID-19 impacts:

Participant Communication | Site Facility Management | Supply Chain | Training Program Study \& Data Integrity | Protocol Specific COVID-19 Risk Assessment

## Rapid Advancement into Phase II:

Celerion's integrated early clinical research allows you to go faster from First-in-Human (FIH) to patient Proof-of-Concept (POC) with expertise.


Virtual trial clinical pharmacology unit (CPU) networks aligned with local bioanalytical laboratories.

Same Project Management Team assigned across the whole program from FIH through later phases drive rapid POC.

Celerion virtual environment includes an experienced team of clinical experts supported by a global network of proven qualified sites and data platforms.

## Current Challenges



Recruitment


Speed to Market


Retention


Cost


Participant Diversity

## The Virtual Operations Environment

Expert Operational Planning Pulls it All Together


## Rapid Process

## Technology Center



Translating your Data into Action-driving Insights

## Key Differentiators



Global sites network with PK sampling capabilities deliver high capacity recruitment for accelerated timelines.
 Global laboratories adjacent to CPUs and sites for rapid POC analysis of biomarkers and pharmacodynamic measures.

## Innovation at Work: FIH > Patient Possibilities

Use time while HV work running to perform sponsor funded pre-screening study to pre-qualify patients for main screening and collect real world data to road test / modify criteria


Ability to spin out to additional site managed by Global Clinical Development

Patient Cohort


## Operational Difference



## E-Data \& Vendor Set Up

- e-Source
- e-Diaries
- e-Consent
- e-Medical records



## Wearable Devices

- Smart phone/pad
- Health monitors
- Skin patches
- Body fluids diagnostic devices
- Cloud access



## Telemedicine

- High speed network
- Platform accessible to sites, subjects and sponsors
- Ability/willingness to support virtual/remote activities


# Site Monitoring Strategy to Keep Investigators Engaged 

Monitoring Frequency - Tailored to Site Enrollment

## Site Communication

Data Monitoring / Query Resolution
Proactive Identification \& Resolution of Site Issues

## Storage \& Analytics

- Investigator Site File, Clinical, BioA \& DMB
- Access to Clinical Safety Data and KPIs
- Reference and Support Materials
- Contact us email link, FAQ documentation, Getting Started Guide, Visual Analytics Help Documentation etc.
- Reports exported as Excel, PPT, PDF, Images etc.


Extensive<br>Scientific Design



CPUs,
Site Networks and Bioanalytical Laboratories


Broad
Global Reach


PM of Global
Virtual Trials

