# 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.



<u>Same Project Management Team</u> 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.

# **Making Virtual Trials a Reality**



### **Current Challenges**







Speed to Market



Retention



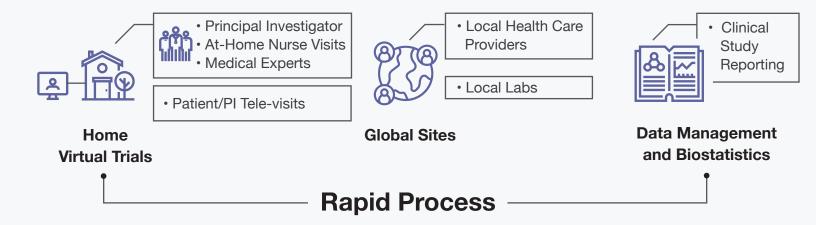
Cost



Participant Diversity

#### **The Virtual Operations Environment**

Expert Operational Planning Pulls it All Together



# **Technology Center**



Translating your Data into Action-driving Insights

# **Making Virtual Trials a Reality**



#### **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 Using internal running to perform **SAD HV** capabilities and sponsor funded pre-screening study to collaborations (e.g. Ability to spin out to **FE HV** pre-qualify patients for with Queens University) additional site main screening and managed by Global collect real world data MAD HV Clinical Development to road test / modify criteria Patient Pre-Screening Study **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

Data Monitoring / Query Resolution

Site Communication

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 Scientific Design



CPUs,
Site Networks and
Bioanalytical Laboratories



Broad Global Reach



PM of Global Virtual Trials