In-Home & Alternative Site Clinical Solutions

Bringing the trial to the patient

Minimising the risk of clinical trial disruption in an evolving environment - COVID-19

The risks COVID-19 may pose to your clinical trial

- Patient safety - increased vulnerability due to infection
- Patient drop-out and non-compliance due to travel restrictions and quarantined areas
- Increased patient anxiety and hesitancy to visit healthcare facilities regularly
- Contamination risk between patients, site and community

Special considerations for operationalising in-home trial services

– If your study protocol needs to be amended our team will work with you to enable in-home patient visits

– Lead time for study start-up could be four to six weeks for North America and up to eight weeks internationally

– Once a study is active, lead time for a visit is five to seven business days

– Government imposed quarantine zones and travel restrictions may limit healthcare professional availability, supply delivery and courier pick-ups

– Alternative logistics to get investigational drugs to patients can be managed by our team

– Your requirements may change overtime and we have the flexibility to scale rapidly

Keeping your clinical trial on track

Deploying ICON's In-Home and Alternative Site Clinical Solutions through Symphony will minimise the impact of COVID-19 on your study.

– In-home services reduce travel needs so patients can stay in your trial, ensuring compliance and data collection

– Decrease the risk of patients coming into contact with the infection at site and being unable to continue on the trial

All healthcare professionals can don personal protective equipment to protect themselves and patients from exposure to COVID-19.

Benefiting the patient, benefiting the sponsor

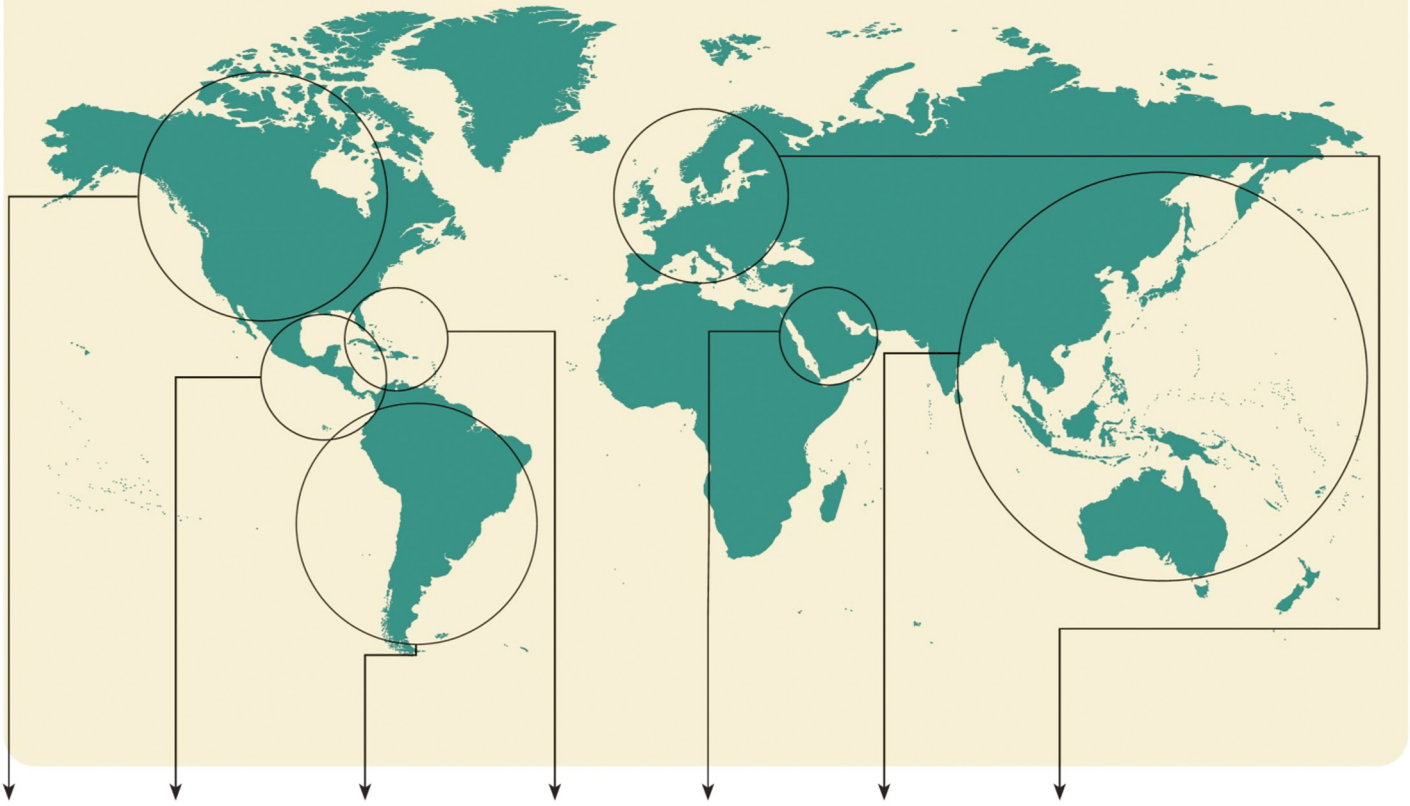
- **Increased comfort and convenience for patients**
- **Enhanced enrollment and retention**
- **Improved compliance**

Extensive range of services to bring the trial to the patient

Symphony Clinical Research has provided services for more than 300 clinical trials. Services are tailored to your specific study requirements and the patient population.

- Study drug administration (infusion, inhaled, injection, topical, oral)
- Blood collection or local and central laboratory processing (PK, PD, safety labs)
- Biological sample collection
- Vital signs, weight and height
- ECG
- Training, coaching, and education for patients (self-administration)
- Timely communication for site safety and reporting
- Assessments
- Patient questionnaires and patient diaries
- Device management
- Visit documentation
- Medical waste disposal
- ICH/GCP, data security and privacy, dangerous goods and other regulatory compliance

Geographical Coverage: In-Home & Alternative Site Clinical Solutions



North America
- United States
- Canada

Central America
- Costa Rica
- Cuba
- Dominican Republic
- El Salvador
- Guatemala
- Honduras
- Mexico
- Nicaragua
- Panama

South America
- Argentina
- Bolivia
- Brazil
- Chile
- Columbia
- Ecuador
- Paraguay
- Peru
- Uruguay

Caribbean
- Bahamas
- Barbados
- Jamaica
- Trinidad & Tobago

Middle East
- Israel

Asia Pacific
- Australia
- India
- Japan
- New Zealand
- South Korea
- Thailand

Europe
- Austria
- Belgium
- Bulgaria
- Croatia
- Czech Republic
- Denmark
- Estonia
- France
- Germany
- Greece
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Case Study: Infection Control

Managing In-home services for immuno-suppressed patients

The Challenge

A midsize biopharmaceutical company was targeting recruitment of 1,122 patients in a phase III global study for cystic fibrosis in patients age 12 and older. The active study period was 96 weeks long and required regular liver function tests.

Cystic fibrosis is a rare, genetic disease, and a mucosal immunodeficiency syndrome and due to a geographically dispersed and highly immunosuppressed patient population, there were concerns about recruiting and retaining patients who would need to travel to a study site. In addition to the travel burden, there were safety concerns with exposing patients to foreign environments and pathogens.

The Solution

Symphony provided in-home clinical trial services to collect and process liver function samples for almost 3,300 visits. Due to the sensitive patient population, every precaution was taken to minimise the risk of infection, with decontamination taking place prior to entering and leaving the patient home.

Risk of infection was managed through steps which included:

- Clinician training
  - All nurses were required to complete training on the sponsor-provided Basic Infection Control and Prevention Plan
- Provision of personal protection equipment
  - All nurses wore gowns, gloves, goggles, and masks during each home visit
  - Hand sanitiser was provided for each nurse
- Centrifuge cleaning procedure
  - If possible, nurses were to centrifuge outside of the patient's home
  - If not possible, the centrifuges were cleaned with provided sodium hypochlorite wipes before and after each use
- Hygiene check reminders
  - Laboratory collection forms included "Important Reminder" boxes about personal protection equipment, proper hand hygiene, and centrifuge cleaning process

The Outcome

The measures were successfully completed in 10 countries across North America, Europe, and Australia. The study was completed on-time and exceeded enrollment.

Symphony CLINICAL RESEARCH

Symphony Clinical Research (Acquired by ICON in 2019) is the leading provider of specialised in-home and alternate site clinical services. We take study visits to patients in all phases and therapeutic areas of clinical trials. We make it convenient for patients to participate in your clinical research by taking study visits to where they live, work, study or play.

For more information on keeping your clinical trial on track:

ICONplc.com/covid-19

ICONplc.com/contact

symphonyclinicalresearch.com

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