Doherty Clinical Trials LTD

Fact Sheet

Advancing novel medicines and vaccines through bespoke clinical trial solutions and human challenge studies

Doherty Clinical Trials accelerates the development of novel medicines and vaccines for key partners and industry clients. Our primary focus is the safety of our participants through the implementation of high-quality and ethical clinical research.

We offer capacity to undertake trials in a range of therapeutic areas with a specific focus on clinical trials for infectious diseases, including human infection challenge studies.

These specialised studies offer unique opportunities during early-phase clinical development of antimicrobial drugs and vaccines and can accelerate key decision making, save millions of dollars and substantially decrease timelines for clinical development.

Our facility is the only unit in Australia specifically commissioned to deliver human challenge trials.

All trials are supported by broad networks of clinical trial expertise, including some of the world's leading hospital clinicians and research scientists.

What does Doherty Clinical Trials offer?

Doherty Clinical Trials focuses on delivering bespoke clinical trial solutions. Our highest priority is the safety of the people choosing to participate in our trials.

We are dedicated to the ethical delivery of high-quality human challenge trials (HCTs), while also addressing cost and time barriers for the development of breakthrough medicines and vaccines.

Although HCTs are the key differentiator for our business, we add value to clinical development through a range of early-phase clinical solutions including Phase I healthy volunteer trials conducted in Australia's only unit specifically established to deliver human challenge studies and backed by high-quality clinician-led research.

We support our partners and clients by offering input on study design, protocol development and comprehensive medical review. In addition to our expertise in infectious disease research, we also provide access to subject matter experts in early-phase development in other therapeutic areas.

Doherty Clinical Trials offers our clients tailored support for their clinical development objectives through access to the deep expertise across Melbourne's Parkville Biomedical Precinct including the Peter Doherty Institute, Royal Melbourne Hospital, Murdoch Children's Research Institute and Walter and Eliza Hall Institute.

Human challenge trials generate critical scientific insights

HCTs are conducted after successful initial Phase I safety studies, and globally have been most often used for diseases such as malaria, influenza and rhinovirus. As a tool, HCTs can assist with valuable information about:[1,2]

- disease mechanisms
- host–pathogen interactions – by taking samples before, during and after infection
- correlates of protection – linking immune or other markers with clinical outcomes
- efficacy – to support further investment in clinical development, HCTs are often considered proof-of-concept studies
- costs and operational complexities that could escalate as clinical development progresses through Phase II and III trials.

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Human challenge trials accelerate delivery of medicines and vaccines

As COVID-19 has taught us, the early delivery of fast-tracked medicines and vaccines has the potential to dramatically reduce the spread and impact of disease on communities.

HCT models are emerging as powerful tools to select promising new vaccines and treatments. HCT models offer unprecedented opportunities in early clinical development, and can accelerate key decision making, save millions of dollars, and decrease the duration of clinical development programs by years.

Doherty Clinical Trials can support you with your clinical objectives using HCTs, which can significantly decrease timelines and costs by:[3]

- enabling profiling of participants before infection so that associations with pre-existing markers such as baseline immunity can be evaluated
- providing early and rapid efficacy data using small cohorts of participants
- delivering more reliable and reproducible results than larger Phase IIb studies where recruitment may be slow or difficult and where population variables are less controlled
- decreasing risks of clinical studies in potentially vulnerable populations
- evaluating unconventional mechanisms of action and or novel routes of vaccine administration
- identifying optimal doses and vaccination schedules for later studies
- providing pivotal efficacy data as part of the registration process
- contributing to design of Phase IIb/III studies.

Our human challenge facility

Doherty Clinical Trials' dedicated facility is currently housed in the building of the former Peter MacCallum Cancer Centre in East Melbourne.

The purpose-built facility contains:

- a 25-bed unit for inpatient clinical research
- specialist containment clinical trial facilities for careful supervision of participants
- six rooms for isolation of trial participants, for example during respiratory virus challenge studies
- screening and outpatient rooms
- a dedicated PC2 laboratory
- a pharmacy and an administrative area.

The clinical trial facility accommodates challenge models for a range of pathogens including:

- respiratory viruses (influenza, RSV, coronaviruses, "other" respiratory viruses)
- malaria
- *Streptococcus pyogenes*
- *Neisseria gonorrhoeae*
- others – such as helminths, HCV and gut pathogens.

1. Balasingam S, Clarke B, Weller C (2023), Use of human infection studies in vaccine development. Wellcome Trust. Online resource. DOI: https://doi.org/10.6084/m9.figshare.21997619.v1
2. Roestenberg M, Hoogerwerf M-A, Ferreira DM, Mordmüller B, Yazdanbakhsh M (2018), Experimental infection of human volunteers. Lancet Infectious Diseases, volume 18, issue 10, E312-E322. DOI: https://doi.org/10.1016/S1473-3099(18)30177-4
3. WHO Expert Committee on Biological Standardization. Sixty-seventh report, Annex 10. Human challenge trials for vaccine development: regulatory considerations, WHO Technical Report Series, No. 1004, 2017. Access: https://www.who.int/publications/m/item/human-challenge-trials-for-vaccine-a10-trs-no-1004

If you would like to discuss how we can help you advance your clinical objectives, please contact:

Dr Andrew Brockway PhD, GAICD
Chief Executive Officer – Doherty Clinical Trials Ltd

andrew.brockway@unimelb.edu.au
+61 435 995 441

Professor James McCarthy FRACP, FAHMS
Chief Medical Officer

james.mccarthy@unimelb.edu.au
+61 414 424 659

792 Elizabeth Street, Melbourne VIC 3000 Australia

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