Case study

SIMBEC-ORION

# Multiple stakeholders collaborate effectively to deliver HV trial in potential treatment for schizophrenia.

**A randomised, blinded, placebo-controlled, single ascending dose (SAD) study and multiple ascending dose (MAD) study to assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of a glutamate receptor enhancer in healthy, adult volunteers.**

## Background

Cardiff University MDI-26478 drug is a potential new treatment for schizophrenia developed by the Medicines Discovery Institute (MDI) at the university.

Our scientists worked with their colleagues at the MDI to design a three-part First in Human study. This required us to collaborate with both the Cardiff University Brain Research Imaging Centre (CUBRIC) for neuroimaging and cognitive assessments, as well as niche CRO, The Science Behind who performed the EEG assessments and collected CSF samples in our Clinical Pharmacology Unit.

## Objectives

- To investigate the safety and tolerability of single and multiple doses of MDI-26478 in healthy participants.
- To investigate the PK & PD of single and multiple doses of MDI-26478 in healthy participants, including the PK/PD relations of single and multiple doses in healthy participants (if supported by the data).
- To investigate effects of MDI-26478 on cognitive functions relevant to Schizophrenia in healthy participants and on neural measures using MEG and fMRI (Parts B-C).
- To identify any metabolite(s) of MDI-26478 following single and multiple doses in healthy participants.

Three part first in human trial required multiple stakeholders to work in partnership.

Regular communication and transparent collaboration was key to success.

Timings of specialist assessments were aligned across the schedules of three organisations to deliver the study

information@simbecorion.com | www.simbecorion.com

## Challenges

- Three-way collaboration, and schedules which needed to be aligned.
- Scheduling of cohorts, particularly in Part B where varying assessments need to be completed by all 3 parties.

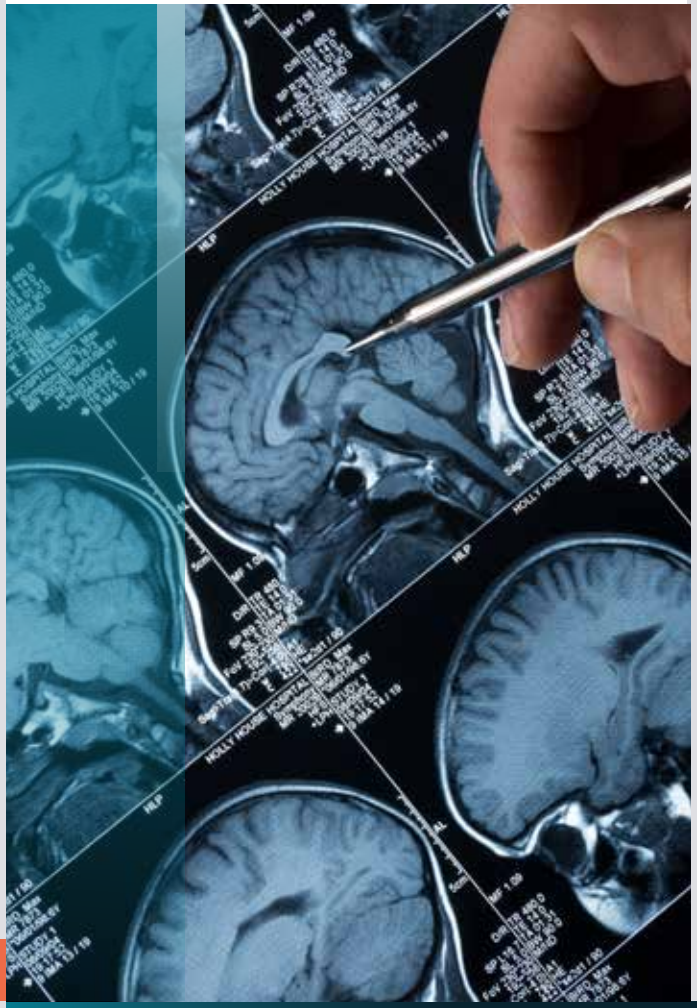
## Solutions

- Increased initial screening period required to accommodate EEG screening and baseline neuroimaging assessments.
- Limited the number of assessments required to be performed at CUBRIC by conducting ECGs, and vital signs at Simbec-Orion.
- Screening forms shared with CUBRIC ahead of participants attending the site enabling the radiographer to provisionally confirm that the participant is eligible for scanning ahead of time.
- High degree of flexibility in accommodating requests regarding the number of participants attending CUBRIC and the preferred dates of their visits.
- Simbec-Orion staff attended CUBRIC during screening and on clinical days to assist with logistics on the day of the assessments.
- Communication channels, both formal and informal were fundamental to success.

## Outcome

Governance was integral to this successful partnership as it supported all of the respective operational teams at a high level. These regular and formal check-ins facilitated rapid decision making, relationship building, strategic planning, issue resolution and performance monitoring.

All three study parts have been initiated, and are currently ongoing.



SIMBEC-ORION

information@simbecorion.com | www.simbecorion.com