CRO

Charité Research Organisation

FOCUSED ON DELIVERING PROOF OF CONCEPT FASTER

Nothing is achieved without focus. Charité Research Organisation focuses on the design and conduct of clinical studies to transition our sponsors from First Time in Human (FTIH) to Proof of Concept (POC) as efficiently as possible.

We share the increasingly common belief that it's possible to learn more about your product in early studies than was historically the case. In addition to evaluating safety and tolerability, we can bring patients into the mix sooner and help you explore efficacy very early on. To do that we provide the capabilities and collaborations modern translational, experimental and exploratory clinical development groups are looking for.

You want to get more out of early clinical development and reach Proof of Concept faster. We can help you achieve that.

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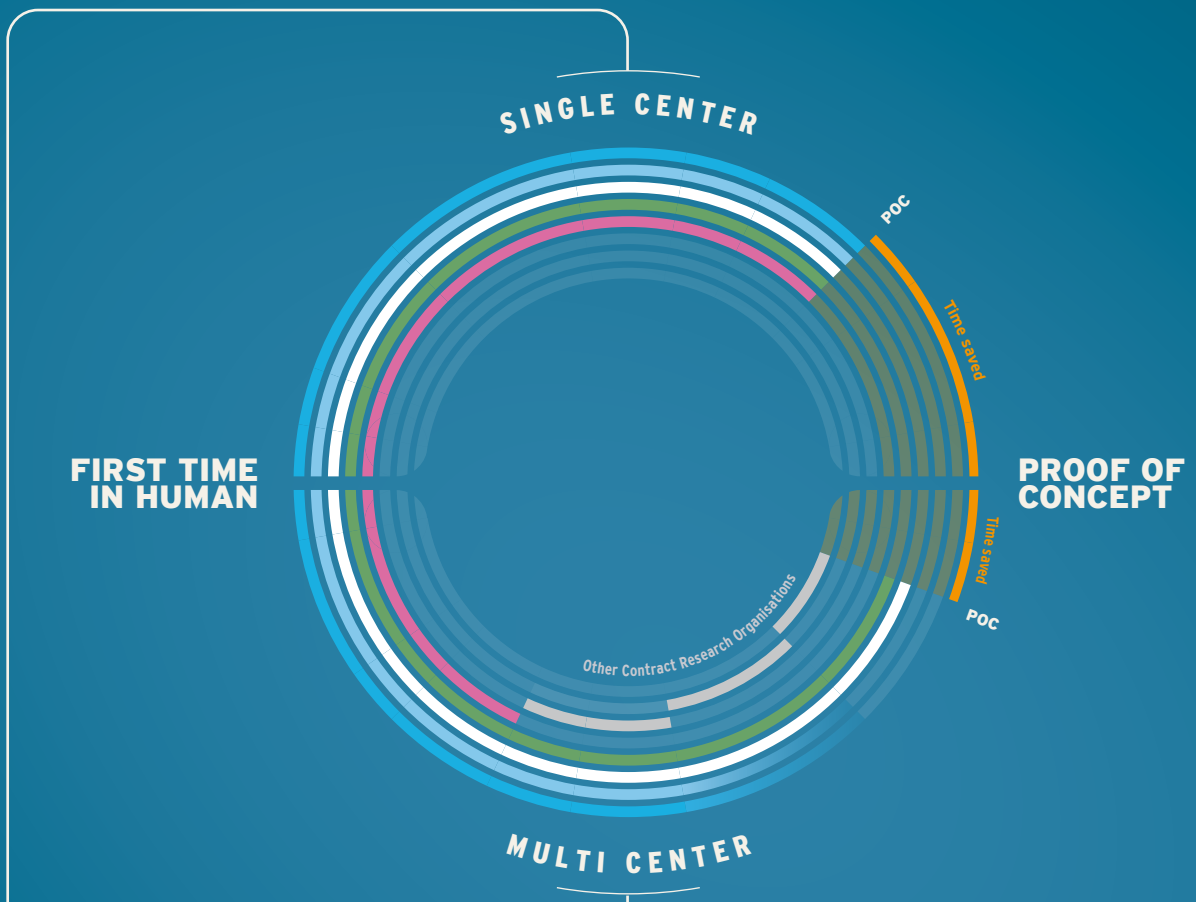
INNOVATION AND EFFECTIVENESS



RECRUITMENT COUNTS · EXPERTISE MATTERS · TECHNOLOGY VISUALIZES · BIOMARKERS EXPOLORE · ORGANISATION EMPOWERS · EXPECTATION REDEFINED

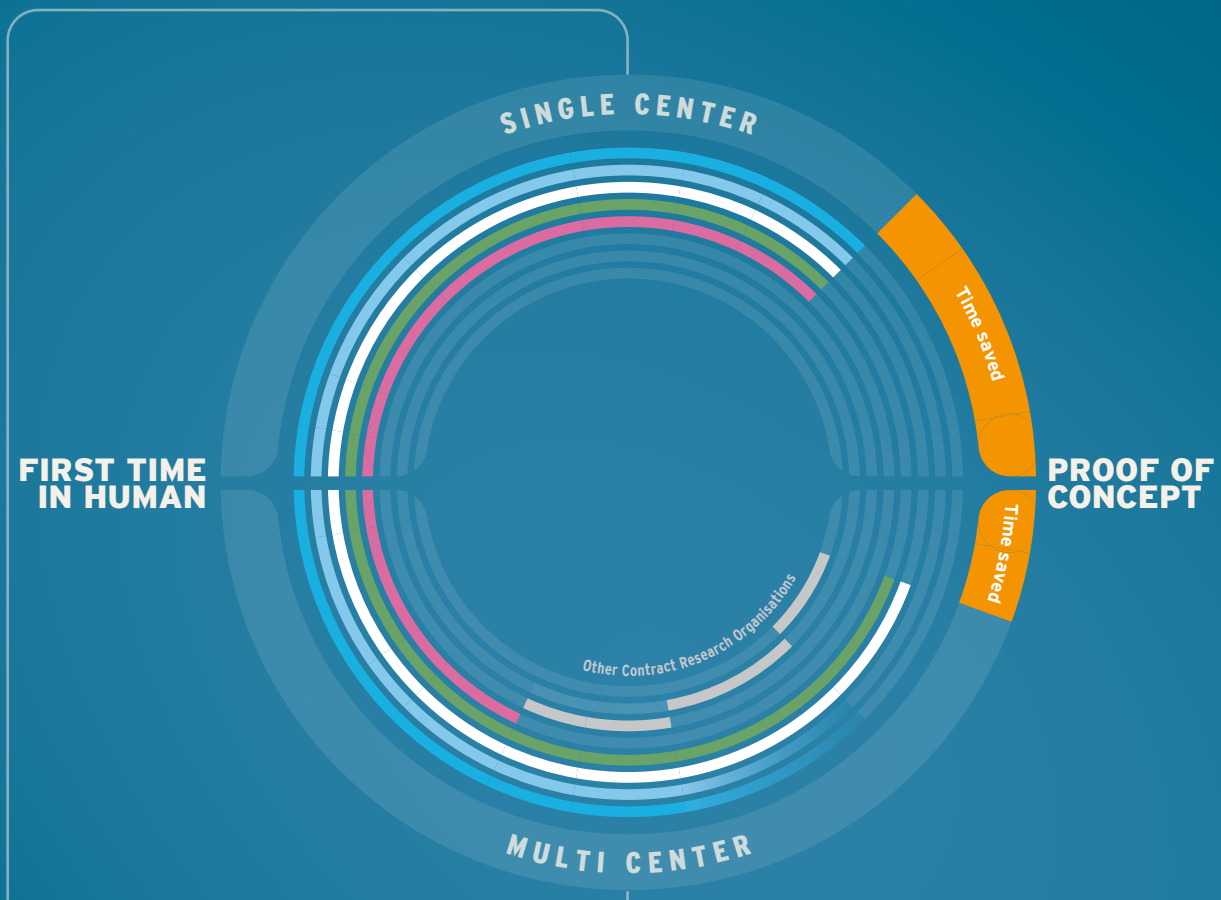
PRESENTING NEW POSIBILITIES

Many things are possible if you approach them in the right way. We have demonstrated time and time again that it's entirely possible to complete FTIH studies in patients using a single-center. We have shown that it's possible to enroll 58 RA patients into a single-center study and beat the timeline that was planned by the sponsor. We have shown it's possible to gain regulatory approval for combined SAD + MAD studies at the FTIH stage and reach first-patient-first-visit earlier than scheduled. We have shown that it's possible to implement studies employing expertise and diagnostic technologies across multiple disciplines, managing them so seamlessly that the sponsor feels they are overseeing a routine healthy volunteer study. Such capabilities open up a world of new opportunities, remove constraints on study design and expand the options available to explore efficacy early.

ENHANCING THE TRADITIONAL APPROACH

When a more conservative approach is desired we are also right there with you. Perhaps there is a need for a steady procession of healthy volunteer studies prior to the first patient study. Perhaps there is a desire to implement the first patient study as a multi-center study, engaging a select number of CROs or a larger number of clinics to get the job done. Rest assured, we are fully capable of undertaking routine healthy volunteer work and completely up to the challenge of being the best recruiting site in early multi-center studies. We can also work with you to ensure that the exploratory potential of early multi-center studies is not limited by the lowest common technology denominator across sites. We have many examples of how exploratory efficacy assessments can be incorporated into multi-center studies to exploit the exceptional access to technologies and expertise we can offer. Whatever your expectations, we can help you improve upon them.

INNOVATION AND EFFECTIVENESS



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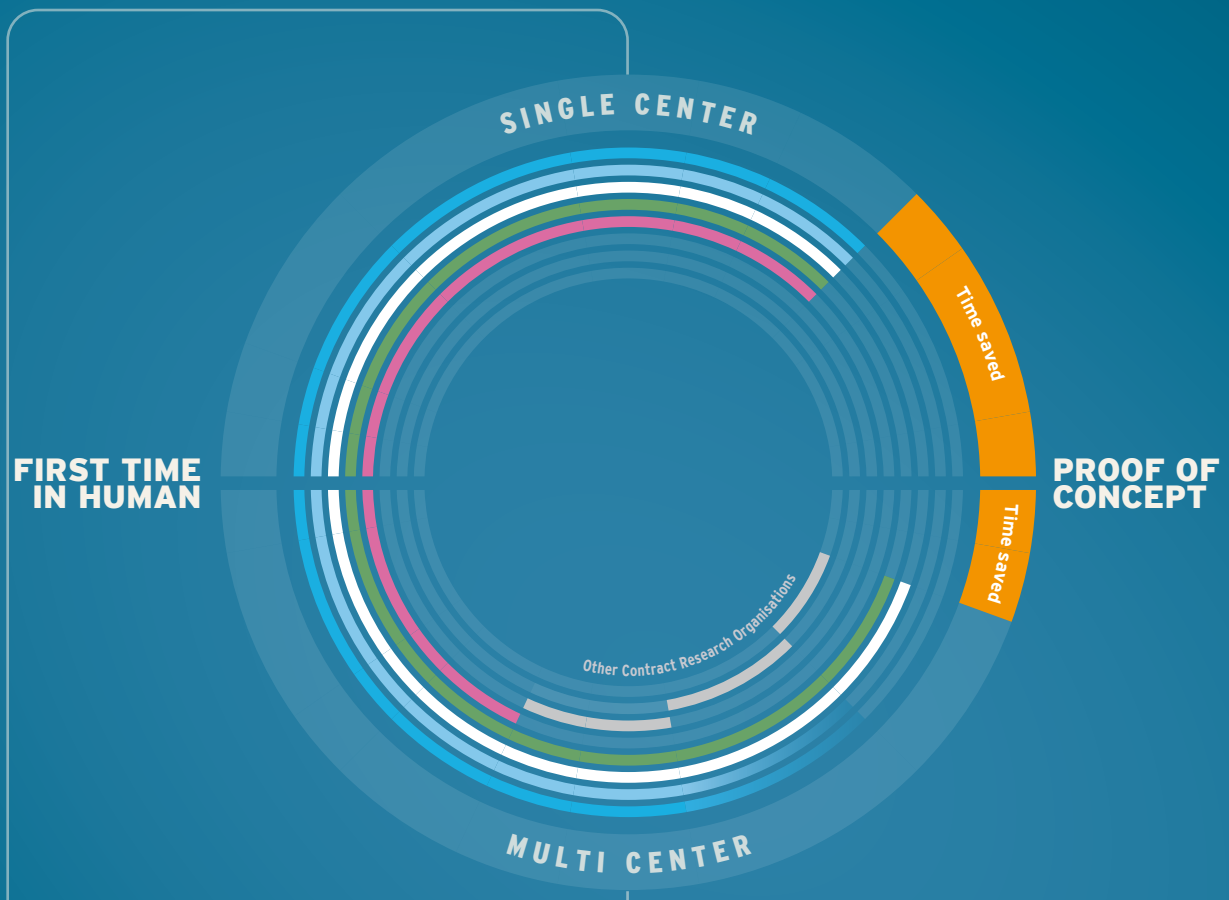

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