

Comprehensive services including strategic gap analysis

A tailored approach to ensure your preclinical package supports your first-in-human (FIH) study

Nucleus Network's preclinical Gap Analysis is a process developed to streamline study startup and ensure your investigational product is fully prepared for Human Research Ethics Committee (HREC) submission. Led by our Chief Medical Officer, Dr Jason Lickliter and Chief Scientific Officer, Dr Graham Wood, this iterative review ensures that every aspect of your preclinical package aligns with the rigorous standards required for first-in-human (FIH) studies.

Key benefits of our preclinical gap analysis



Early gap identification

Detect any areas that require further data in your non-clinical Data or Protocol Design before submission.



Maximized HREC approval chances

Ensure your submission meets the highest standards, giving your study the best chance for timely approval and smooth startup.



Proactive problem solving to avoid delays

Anticipate and resolve HREC concerns early, helping you prevent costly delays or resubmissions and keeping timelines on track.



Expert guidance from industry leaders

Benefit from the support of Dr Jason Lickliter, Dr Graham Wood and our seasoned team to navigate every regulatory requirement.



Enhanced data confidence and integrity

Confirm your preclinical package meets ICH M3(R2) or S6(R1) guidelines, ensuring data quality and overall regulatory compliance.



Supporting every step of your FIH clinical journey

Nucleus Network offers end-to-end support for your clinical trial, starting with a complimentary gap analysis to ensure your preclinical package is HREC-ready.

Our team manages complex regulatory submissions to prevent delays, and we handle patient recruitment and retention through extensive networks and a participant centered approach.

With expert coordination across all trial phases, our team ensures seamless execution. Located within major academic hospitals, our units provide immediate emergency access and maintain the highest safety and compliance standards, supporting your study at every step.

How it works

A structured process for stronger submissions

Our gap analysis process is designed to be thorough, streamlined, and highly effective, ensuring your submission is as strong as possible. Starting with your initial preclinical data and continuing through to the final protocol and Investigator Brochure, we guide you at each step. With expert insights from Dr Jason Lickliter, Dr Graham Wood and our dedicated team, we help you identify and address gaps, refining your submission for a seamless HREC approval process.

Preclinical gap analysis process

1 Initial sponsor consultation

Our team starts by addressing any initial questions the sponsor may have about HREC requirements and the necessary preclinical data.

2 Submit preclinical data

Sponsor provide their investigational product's nonclinical data, and protocol. When the Investigator Brochure (IB) is shared, our review deepens further.

3 Comprehensive review

Dr Jason Lickliter, Dr Graham Wood and our expert team review the IB to ensure alignment with ICH M3(R2) or S6(R1) guidelines and evaluate the package for FIH protocol readiness.

We assess factors such as:

- Inclusion of required GLP studies
- Appropriate species selection, especially for biologics Toxicology study length relative to FIH protocol dosing
- Compliance with NOAEL or MABEL calculations per EMA and FDA
- Alignment of contraception requirements with reproductive toxicology studies
- Additional safety procedures, if needed, based on safety pharmacology data
- Consistency of FIH study design with pharmacokinetic and pharmacodynamic data

4 Receive customized feedback

Our team delivers a detailed report highlighting specific areas that may need improvement.

5 Iterative review and finalization

As the study progresses, we refine our insights until final versions of the Investigator Brochure, protocol and ICF are complete, ensuring that your submission is prepared for a successful HREC review.





Why Nucleus Network?

Nucleus Network is trusted by sponsors worldwide for our high standards, deep expertise, and ability to deliver timely, high-quality results.

With over a decade of experience and 1,000+ HREC submissions, our team supports your study from planning to approval, with clinics strategically co-located alongside leading tertiary hospitals: The Alfred Hospital in Melbourne and Royal Brisbane and Women's Hospital in Brisbane.

Prepare your study for success



Dr Jason Lickliter
Chief Medical Officer

As Chief Medical Officer, Dr Jason Lickliter has extensive experience in clinical trial management, with a focus on early-phase and first-in-human studies. Having led over 1,000 successful HREC submissions, Dr Lickliter provides critical medical and regulatory insights to optimize study protocols for HREC approval. His leadership ensures that every study at Nucleus Network is scientifically sound and adheres to the highest regulatory standards.



Dr Graham Wood
Chief Scientific Officer

Dr Graham Wood brings extensive scientific and regulatory expertise to Nucleus Network as Chief Scientific Officer. With a deep background in clinical pharmacology and drug development, Dr Wood specializes in preclinical assessment and protocol design, ensuring investigational products are ready for FIH studies. His guidance is instrumental in aligning preclinical packages with international standards, supporting the smooth progression of clinical trials.

Partner with Nucleus Network and leverage our full suite of services

Contact us today to partner with Nucleus Network and benefit from our comprehensive suite of services, including an in-depth gap analysis to prepare your study for HREC approval and clinical startup.

Contact Nucleus Network

 partnering@nucleusnetwork.com

 nucleusnetwork.com/sponsors



Advancing medicine, improving lives.