

# CLINICAL RESEARCH IN PRACTICE

## Exploring Study Design, Ethics, Participant Engagement And Clinical Trial Coordination in a Hospital-Based Research Environment at HSNRI



Presented by: Swancy Avaiya, Biotechnology Technologist, Canadore College



### PROJECT OVERVIEW

At Health Sciences North Research Institute (HSNRI), clinical research studies were explored within a hospital-based research environment. The experience provided exposure to how clinical trials are designed, managed, and supported through collaboration between research teams, healthcare professionals, and study sponsors.

Clinical trials are structured research studies involving human participants that evaluate the safety, effectiveness, and outcomes of new treatments, drugs, or medical interventions. It was learned that clinical trials follow a step-by-step phased process, beginning from early laboratory and pre-clinical development and progressing through multiple phases where safety, dosage, and effectiveness are assessed in increasing participant groups before reaching broader clinical application.

The clinical research process was observed including how protocols are developed, ethically reviewed, and organized prior to participant involvement. Key processes such as documentation, data management, and regulatory compliance were essential in ensuring accuracy, safety, and consistency within a real healthcare setting.

Exposure was also gained to site-level clinical research activities, including participant pre-screening processes and initial study coordination. It was observed how research teams prepare for participant engagement by ensuring clear communication, ethical considerations, and appropriate understanding of study requirements before enrollment.

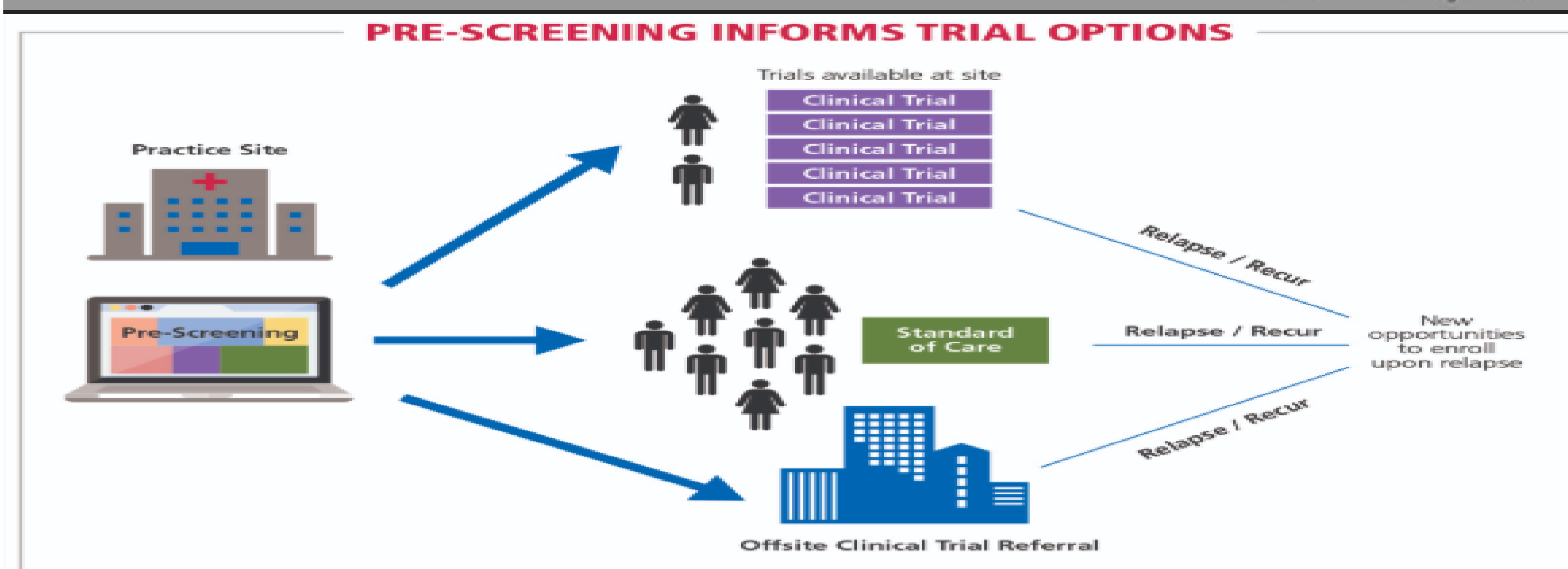
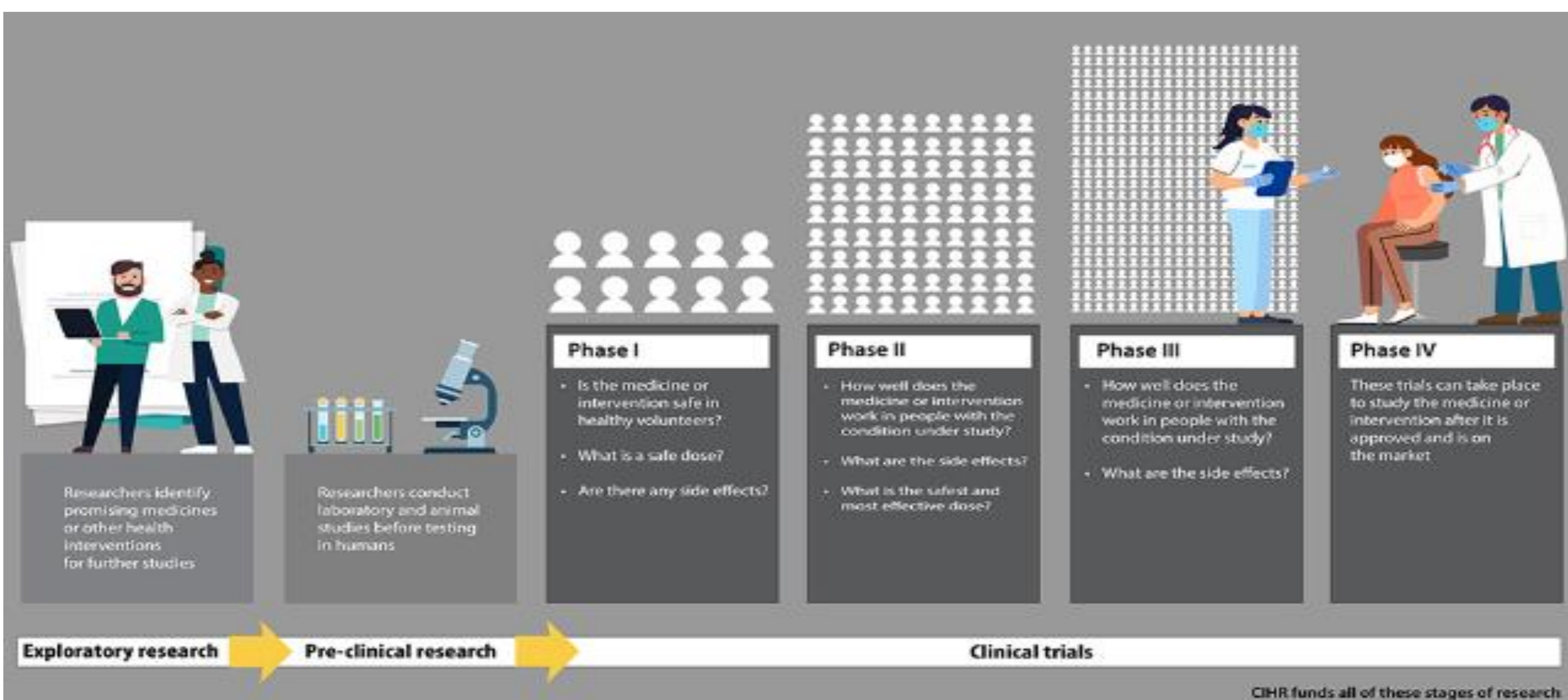
### OBJECTIVE

- Support and coordinate activities under the Canadian Remote Access Framework for Clinical Trials (CRAFT), a national initiative expanding clinical trial access across Canada through hospital and satellite sites
- Understand how clinical research studies are designed, coordinated, and conducted in a hospital-based research environment
- Observe clinical trial workflows including study setup, participant pre-screening, and informed consent processes
- Learn how inclusion and exclusion criteria are applied to ensure participant safety and maintain study integrity
- Gain exposure to communication between sponsors, research teams, and multiple sites in supporting clinical trial operations
- Gain practical experience with Good Clinical Practice (GCP), clinical documentation, regulatory compliance, and structured research workflows
- Understand clinical trial progression from laboratory research to human studies through Phase I-IV development

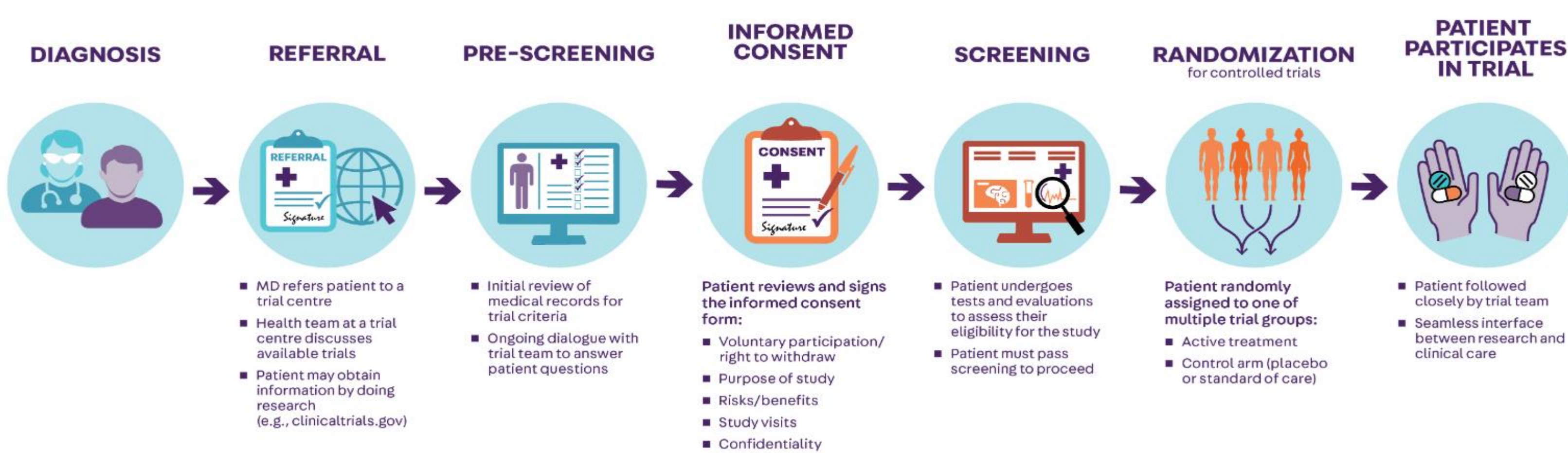
### CHALLENGE EXPERIENCED AND APPROACH USED

During the internship, challenges were observed during clinical trial pre-screening and coordination activities at the study site. Participant hesitation was commonly seen due to misconceptions about clinical research, including fears of unsafe treatment or being treated as "test subjects." Strict inclusion and exclusion criteria also made participant identification difficult, as eligibility was limited for safety and ethical reasons. In addition, limited awareness of clinical trials affected understanding during initial participant interactions.

To address these challenges, involvement was seen in structured communication and study coordination processes. Investigator Meetings (IM) were helpful to understand study protocol's updates, and ensure consistent application of procedures across sites. Participant discussions were supported by providing simple explanations of trial purpose, safety measures, and ethical safe guards to improve understanding and build trust. Eligibility criteria were applied strictly during pre-screening to ensure patient safety, while coordination between sponsors and research teams helped maintain consistent trial conduct and accurate information flow.



### PATIENT PATH TO CLINICAL TRIALS



### REFERENCES

Canadian Institutes of Health Research. (n.d.). *What are clinical trials?* [Infographic]. <https://cihr-irsc.gc.ca/e/52988.html>  
 American Cancer Society Cancer Action Network. (n.d.). *Figure 9. Pre-screening informs trial options* [Image]. <https://www.fightcancer.org/figure-9-pre-screening-informs-trial-options>  
 McGill University Health Centre. (n.d.). *Patients in clinical research unit* [Image]. <https://cru.mcgill.ca/patients/>  
 National Institutes of Health. (n.d.). *The basics: NIH clinical research trials and you*. <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>  
 National Institute on Aging. (n.d.). *What are clinical trials and studies?* <https://www.nia.nih.gov/health/clinical-trials-and-studies/what-are-clinical-trials-and-studies>  
 \* AI was used to assist with writing, editing, and organizing the poster content.

### OVERALL IMPACT

Clinical research plays a key role in improving patient care and advancing medical knowledge. One important outcome of clinical trials is that even when a new treatment does not show better results, the study still provides valuable evidence. This helps confirm that the current standard of care is effective, safe, and reliable, which is equally important in improving healthcare practice.

Clinical research supports multiple groups within the healthcare system. Patients benefit through access to new treatment options, closer monitoring, and safer, evidence-based care. Healthcare providers benefit from improved clinical evidence that supports better treatment decisions. Researchers and sponsors use trial data to develop, evaluate, and refine new medical therapies. Clinical research assistants and site teams support this process by ensuring studies are properly coordinated, data is accurately collected, protocols are followed, and patient safety is maintained throughout the trial.

Overall, clinical research is important because it ensures that medical treatments are tested in a safe, ethical, and structured way before becoming part of standard healthcare. It helps improve current treatments, validate existing practices, and contribute to continuous improvement in patient outcomes