Executive Summary: Clinical Trials Acceleration Platform (CTAP)

Vision and Strategic Opportunity

Advances in artificial intelligence, molecular biology, and biomanufacturing are rapidly expanding the pipeline of vaccines, biologics, and cell therapies. However, the fundamental bottleneck to realizing patient benefit remains human clinical trials—specifically the speed, integration, and cost of trial initiation, recruitment, and biospecimen handling.

The **Clinical Trials Acceleration Platform (CTAP)** will establish a world-class, AI-enabled, health-system-embedded infrastructure that links discovery to patients to real-world impact. CTAP is not merely a facility; it is a transformative operating system for translational science. By leveraging Alberta's unique assets—a single-payer health system with a province-wide electronic medical record (Connect Care) and Turing Award-winning AI expertise (Amii)—CTAP will position the University of Alberta (UofA) as a national leader in next-generation clinical trials.

The Core Innovation: A Continuous Learning Ecosystem

The central innovation of CTAP is to treat clinical trials as a **continuously learning, AI-enabled system** rather than episodic, stand-alone projects. This infrastructure integrates five tightly coupled domains to create a seamless feedback loop between bench and bedside:

1. The Clinical Trials Acceleration Hub (Governance & Operations)

Led by **University of Alberta Clinical Trials (UACT)**, this hub acts as the central "control tower," uniting partners including the Kipnes Health Research Institute, the Women and Children's Health Research Institute (WCHRI), and the Canadian VIGOUR Centre.

- **Innovation:** CTAP consolidates the clinical trial lifecycle by leveraging existing initiatives, funding levers and centralized coordination to ensure a seamless experience for industry and principal investigators.
- **Ownership:** It moves beyond administrative support to active management of the trial pipeline, integrating regulatory navigation, budgeting, and feasibility via the **CRAIDL** AI engine.

2. Advanced Biorepository & Manufacturing (The Science of Storage)

Moving beyond the traditional model of purchasing siloed freezers, CTAP will implement a **centralized, automated biobanking system** modelled after leading UK and US biobanks. This

infrastructure focuses on the *science of biospecimen storage*, with an emphasis on standardization, biosecurity, and sample utility.

- **Centralization & Efficiency:** We will reduce the campus-wide footprint of energy-intensive -80°C freezers by transitioning to high-density, automated cryogenic systems managed by the **Canadian BioSample Repository (CBSR)**.
- **Quality & Standardization:** By automating aliquoting and tracking, we ensure consistent cryopreservation standards across all research and clinical studies, maximizing the utility of every donor sample for future multi-omics discovery.
- **Manufacturing:** This core integrates directly with **Alberta Cell Therapy Manufacturing (ACTM)** to provide GMP production of biologics and cell therapies, ensuring "made-in-Alberta" discoveries can move rapidly into first-in-human trials.

3. Agentic AI & Data Engine (CRAIDL)

CTAP will develop and deploy **CRAIDL (Clinical Research Assistants for Intelligent Design and anaLysis)**, a suite of AI agents capable of augmenting every stage of a randomized clinical trial.

- **Generative Trial Design:** AI agents will assist with protocol development, optimization of inclusion/exclusion criteria, and generation of a synthetic control arm using real-world data.
- **Operational Acceleration:** Targeting a reduction in start-up timelines by 40–50% and reducing eligibility screening time by up to 78%.
- **Data Integration:** Powered by an AWS-enabled health data clean room and the Alberta Machine Intelligence Institute (Amii), this engine secures and analyzes data from Connect Care, ensuring privacy-preserving recruitment and long-term follow-up.

4. Discovery-to-Trials Molecular Phenotyping

To drive precision health, CTAP embeds deep molecular phenotyping directly into the trial workflow.

- **Mechanism & Biomarkers:** Leveraging the **Cryo-EM facility**, **the Glycomics Institute of Alberta, and the Metabolomics Innovation Centre (TMIC), CTAP enables** simultaneous evaluation of clinical outcomes and deep mechanistic data (e.g., metabolic or glycomic changes) within the same trial infrastructure.

5. Decentralized & Inclusive Trial Technologies

- **Equity & Access:** Working with the Indigenous Clinical Trials Unit, utilizing eConsent, wearables, and remote monitoring to enable decentralized trials that reach rural and Indigenous communities, aiming to double recruitment efficiency and equity.

Flagship Research Drivers

While serving as a university-wide core, CTAP will initially anchor its capabilities in four high-impact domains:

1. **Neuro-Immunology & Infection:** A new initiative in partnership with UCSF Quantitative Biosciences Institute to explore the infectious disease origins of neuroimmune disorders like MS, long COVID, and others, building on the PRAIRIE-Hub and SPP-ARC.
2. **Vaccines & Pandemic Preparedness:** Structure-guided vaccine design and to accelerate early-phase trials (i.e., Hepatitis C vaccine program).
3. **Precision Population Health:** Cardio-renal-metabolic disease trials utilizing AI-based risk prediction and Indigenous-led governance streams.
4. **Pediatric Rare Disease:** Serving as a western hub for **RareKids-CAN**, integrating genomic discovery with clinical care.

Impact and Sustainability

By 2031, CTAP will transform the UofA into a permanent national clinical trials infrastructure hub.

- **Economic Impact:** Attracting industry-sponsored trials and global investment by offering a streamlined, "one-stop" jurisdiction for advanced therapy testing.
- **Health Impact:** Shortening the path from discovery to patient benefit and improving outcomes at both individual and population scales.
- **Financial Sustainability:** The platform is designed for long-term viability through cost-recovery user fees (biobanking, GMP manufacturing), industry contracts attracted by CRAIDL efficiency, and alignment with national funding networks (ACT-AEC, PRAIRIE Hub).

This proposal requests **$10 million** to build the physical and digital backbone of this vision—not just to house equipment, but to engineer the future of rapid, equitable, and data-driven clinical research.