**CanPREG: A National Primary Data Infrastructure for Pregnancy Research**

**CanPREG** is a groundbreaking pan-Canadian infrastructure designed to fill a critical data gap in maternal-child health by systematically collecting prospective, real-time, patient-reported data (PRD) from pregnant individuals, their partners, and children through a bilingual mobile application. Developed as the final pillar of the CAMCCO initiative, CanPREG complements the CAMCCO-Research real-world data platform by capturing variables absent from administrative data—such as folic acid use, smoking, alcohol, illicit drug use, breastfeeding, OTC medication intake, symptom patterns, and partner exposures. All data are securely stored in a centralized cloud server hosted at CHU Ste-Justine and are designed for linkage with secondary databases, including community pharmacy records and provincial cohort data. Beyond data collection, CanPREG features an integrated AI Hub for automated machine learning–driven analytics, predictive modeling, and medication safety signal detection. By enabling the proactive identification of adverse events and advancing equitable, patient-centered research, CanPREG will be the first infrastructure of its kind globally—positioning Canada at the forefront of pregnancy pharmacoepidemiology, personalized medicine, and perinatal public health research.

**Bumpie: A Technologically Advanced Platform for Personalized Digital Health in Pregnancy**

**Bumpie** represents the technological core of the CanPREG ecosystem, functioning as a smart, bilingual mobile application built for real-time data capture, individualized patient engagement, and digital health innovation in pregnancy. Developed through extensive user research, competitor analysis, and prototype testing, Bumpie incorporates a range of novel functionalities, including intelligent medication tracking (via barcode scanning and photo input), customizable reminders, digital health diaries, validated symptom, medical history and mental health questionnaires, and gamified engagement features. Its design is both evidence-based and culturally sensitive, prioritizing secure data handling, anchored in behavioral psychology principle, and the ability to link seamlessly with external health systems (long-term pipeline). What sets Bumpie apart is its unique dual purpose: it serves not only as a digital companion to individuals throughout their pregnancy and the postpartum period, but also as a **research-grade data collection interface** for the national CanPREG registry. With a usability rating of 92.5% in early testing, and integration planned with CAMCCO-Outreach’s educational content, Bumpie transforms mobile health from passive tracking to active, AI-supported engagement—blending public health, clinical care, and research into one cohesive, patient-centered tool. This innovation is the first of its kind in Canada. Bumpie’s prototype is set to be finalized in August 2025 and deployed early 2026.

**Bumpie AI Companion: A High-Risk, High-Reward Digital Health Innovation Powered by INNOV-Bot**

As part of the INNOVATE program’s mission to transform medication safety and clinical decision-making during pregnancy, we propose the **Bumpie AI Companion**—a conversational digital health assistant *powered by INNOV-Bot*, embedded within the Bumpie platform. This system uses advanced natural language processing (NLP), generative AI, and real-world data to deliver personalized, bilingual support to pregnant individuals in real time. At its core, **INNOV-Bot** is a dual-layered artificial intelligence infrastructure. The **chatbot interface** enables users to ask health-related questions, share symptoms or medication use, and receive tailored guidance adapted to their gestational age and clinical context – as populated within their profile in Bumpie. Behind this, the **automation engine** synthesizes a wide array of knowledge sources, including real-world data (RWD) from CAMCCO-Research, patient-reported/generated data (PRD/PGD) from CanPREG, outreach materials from CAMCCO-Outreach, and curated evidence and findings from INNOVATE. The system’s primary function is not just prediction or signal detection, but intelligent, context-aware knowledge retrieval: when a question is posed, it identifies and delivers the most relevant, ethically validated information to support informed care.

**A foundational feature of the Bumpie AI Companion is its ability to assess and respond to the user’s risk perception before communicating any clinical or scientific information.** Drawing from behavioral science and patient-centered communication principles, the chatbot will first evaluate how the user understands and frames the potential health concern, such as perceived severity, uncertainty tolerance, or emotional tone, all prior to delivering information. This approach enables the system to modulate both the content and tone of its responses, offering layered explanations, contextual reassurance, or escalated follow-up where appropriate. This personalized framing of information ensures that guidance is scientifically accurate, psychologically adapted and ethically responsible. Patient data collected via the Bumpie App (e.g., symptoms, medication entries, sociodemographic context) will be part of the CanPREG database, and will, with appropriate consent, contribute to training and refining INNOV-Bot’s models, thus enhancing personalization and signal sensitivity across the population. However, information shared within the chatbot interaction itself is treated as **confidential and ephemeral**, with no persistent storage or external use. This **differentiated data strategy** upholds ethical standards, supports OCAP principles, and ensures users retain control over how their data is used.

This proposed infrastructure represents a **high-risk, high-reward technological innovation**. It combines sensitive patient engagement, AI-driven personalization, and cross-disciplinary data integration in one system. Challenges include ensuring transparency, maintaining user trust, and deploying this initiative with a robust ethical and legal framework at its core. However, the anticipated impact is profound: INNOV-Bot offers a scalable, ethically governed infrastructure to accelerate teratogenic signal detection, enable real-time personalized guidance which is a needed tool given the state of the Canadian healthcare system, and translate complex research into accessible, actionable care. By embedding INNOV-Bot into Bumpie, we operationalize a learning healthcare framework rooted in equity, co-creation, and precision public health. This initiative not only redefines how evidence is mobilized in maternal care, but it also positions Canada as a global leader in responsible, AI-powered digital health innovation for pregnancy.