IHI Call Days | Call 9

Biomarker and Behavioral Evidence for Advanced Clinical Outcomes and Neurological Precision Healthcare in Migraine using Multimodal Data Integration (BEACON)

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Link to the IHI brokerage platform:

- Proposal sharing tool
- https://ihicalldays2024.converve.io/index.php?page=ed_profile#networking
- Participant profile: https://ihicalldays2024.converve.io/index.php?page=ed_profile&params%5Btab%5D=networking#persons

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Challenges and objectives

- **What Problem(s) are We Trying to Solve?**

- **Migraine Burden:** High-impact chronic condition with limited effective treatments.

- **Personalization Gap:** Standard treatments don't account for diverse patient responses which especially harms women.

- **Data Fragmentation:** Lack of integration across pharma, digital health, and patient data limits personalized care.

- **Which IHI Specific Objective(s) are We Addressing?**

- **SO1:** Enhance understanding of migraine determinants by integrating biomarkers, behavioral data, and Real-World Evidence (RWE) to capture individual variability in disease progression and treatment response.

- **SO2:** Bridge research across pharmaceutical, digital health, and patient advocacy sectors, creating unified predictive tools and data platforms for effective cross-sector collaboration.

- **SO4:** Leverage digitalization through machine learning to generate actionable insights for precision medicine.

- **SO5:** Set new standards for evaluating personalized neurological care.

- **Which Unmet Public Health Need are We Addressing?**

- **Personalized Migraine Treatment:** Addressing the need for targeted therapies that account for patient-specific biological and behavioral factors, reducing the burden of trial-and-error treatment.

- **Healthcare Cost Reduction:** Improved outcomes lower recurring care needs.

- **Patient Autonomy:** Building on FACILITATE's patient-centered consent and data-use models, BEACON ensures ethical, transparent secondary data use that respects patient autonomy while fueling innovation.

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Your approach to solve the problem

- **Targeting Migraine's Complexity:** BEACON develops predictive models that address migraine's variability, bridging gaps left by traditional treatments to meet the need for individualized care.

- **Leveraging Secondary Data for Precision:** By integrating clinical trial data and Real-World Evidence (RWE), BEACON enhances treatment accuracy and improves patient outcomes.

- **EMA-Aligned Innovation:** BEACON's multimodal data and machine learning strategy aligns with the EMA's vision for regulatory data insights, streamlining faster regulatory approvals.

- **Cutting-Edge AI with BINNs:** Biologically informed neural networks (BINNs) support data-driven treatment decisions, addressing public health needs in a forward-thinking, data-centric manner.

- **Continuous RWE Integration:** Seamlessly aligned with GDPR and European Health Data Space (EHDS), BEACON ensures compliance and supports ethical patient data use.

- **Building on FACILITATE's Legacy:** Incorporating FACILITATE's flexible consent models positions BEACON as a mature, patient-centered project with practical, regulatory-ready applications.

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Is your project suitable for IHI?

IHI aims to fund large-scale projects focusing on health innovation. Explain why a public private collaboration is essential to develop your proposal

Why BEACON Fits IHI's Goals:

BEACON embodies IHI's commitment to collaborative, pre-competitive health innovations that leverage real-world data and patient-centered approaches. Built on FACILITATE's ethical data frameworks, BEACON emphasizes transparency, patient autonomy, and data security, aligning with IHI's vision for an integrated health innovation ecosystem.

Public-Private Collaboration

BEACON's need for a public-private collaboration is strong,

- **Pharma** for its clinical trial data and R&D resources,
- **Patient associations** to integrate patient-centric insights and increase trust,
- **Digital health and AI experts** to build the machine learning infrastructure.

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- **Where do you see the contribution of industry in your proposal? Why do you require different health industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)? Impact of contribution of industry to the BEACON project:**

1. **Partner in Accelerated Drug Development**: By leveraging rich multimodal datasets, pharmaceutical companies can enhance the precision of clinical trials, improving patient selection and reducing the time needed for drug development. Predictive models will also help in stratifying patients for clinical trials, leading to more successful outcomes.

2. **Create Real-World Applicability**: BEACON's integration of RWE will allow pharmaceutical companies to validate drug efficacy and safety in real-world settings. This can strengthen regulatory submissions and improve the chances of approval by demonstrating real-world benefits and adaptability of their therapies.

3. **Help provide Long-term Value through Scalable Models**: BEACON's methods can be applied beyond migraine to other neurological and chronic diseases. This scalability asks pharmaceutical companies to leverage the project's innovations across a broader therapeutic landscape, extending the value of their participation.

4. **Help create Innovative IP Management**

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Outcomes and Impact

- What do you expect out of your proposal in terms of concrete results/outcomes and impact?

Concrete outcomes and key deliverables that project BEACON as a high-impact initiative: **Outcome-Driven Focus** with a dual impact on both healthcare and industry competitiveness

- **Patient-Centered Precision Medicine:** BEACON's predictive models will enhance patient quality of life, with an emphasis on reduced symptom recurrence and healthcare visits. This aligns well with IHI's push for impactful healthcare outcomes.
- **Reduced Healthcare Burden:** Effective, personalized treatments will lower healthcare costs by minimizing emergency visits and reducing the need for repetitive consultations.
- **Value to Industry Partners:** such as faster drug development, reduced trial costs, and market differentiation—would clearly show.

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Outcomes and Impact

- How does your project proposal contribute to the expected benefits for patients?

- **Predictive migraine stratification models,**

- **Patient-centered clinical decision tools, and Patient-Centered Data Transparency**: Built on FACILITATE's flexible consent models, BEACON sets a new standard for ethical data use, ensuring trust and smooth integration into healthcare systems

- **Reduced trial-and-error in patient treatment selection will help stakeholders see tangible value.**

- How does your project proposal contribute to strengthening the competitiveness of the Union's health industry?

- **BEACON's Scalable Model:** BEACON's model has the potential to be adapted for other chronic conditions beyond migraine. This scalability aligns with IHI's goal of broad healthcare transformation and could attract partners with diverse interests in chronic care.

- **Regulatory Alignment and Data Transparency:** BEACON has an important role as a regulatory-compliant, providing scalable solution that could set new standards for data transparency and ethical patient consent in clinical trials across Europe.

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Expertise and resources

- We have:
  - Multimodal data integration (genetics, proteomics, neuroimaging), machine learning, RWE application, patient advocacy (aligned with FACILITATE's flexible consent and data privacy frameworks).

- We are looking for:
  - Specialists in digital health, additional EFPIA members for funding collaboration, patient organizations, and regulatory advisors to optimize clinical and ethical compliance.

If you are bringing in-kind contributions (IKOP* and IKAA** for Private members, cash or in-kind contributions for Contributing Partners), state it clearly.

* IKOP - in-kind contributions to operational activities
** IKAA - in-kind contribution to additional activities

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