IHI Call Days | Call 12

BRIDGE-AM: Building Real-world Insights and Digital Generation of Evidence for Additive Manufacturing (AM/(3DPrinting)) in Healthcare

Contact person name: Naomi L Nathan

Organisation Mobility|Medical goes Additive e.V. (MGA)

E-mail: naomi.nathan@mga-net.com

Link to the IHI brokerage platform:

- Proposal sharing tool: Link
- Participant profile: Link

mga

innovative health initiative

Challenges and objectives

- **Addressing IHI JU Challenges:**
- **Primary IHI Specific Objectives Addressed: 4 and 5**
- **Secondary Objective: 2** (Integration of fragmented health R&I efforts)

- What problem(s) are you trying to solve
  - **Evidence Gap for Personalized Manufacturing**: Current RWE methodologies cannot assess interventions where every product is unique. Traditional clinical trials and HTA frameworks assume standardized products with batch production, this fails for patient-specific 3D-printed implants, prosthetics, and surgical guides.
  - **Fragmented Value Assessment**: No framework exists to evaluate the combined value of: Custom-manufactured medical devices, digital design and planning tools, point-of-care manufacturing, and integrated monitoring systems (prevents healthcare systems from making informed adoption decisions).
  - **Implementation Uncertainty**: Healthcare providers lack evidence on: ROI of establishing in-hospital AM capabilities, quality assurance for distributed manufacturing, optimal patient selection for personalized devices, and long-term outcomes of customized interventions

innovative health initiative

Challenges and objectives

- **Objective 4 - Digitalization and Data Exchange:**
  - Creating first European platform linking AM produced customized medical solutions with clinical outcomes
  - Developing standardized data formats for capturing personalization parameters and their clinical impact
  - Establishing interoperable systems connecting design software, manufacturing equipment, and hospital information systems
  - Implementing privacy-preserving analytics for batch-of-one products

- **Objective 5 - New Assessment Methodologies:**
  - Developing novel evaluation frameworks specifically for customized medical solutions
  - Creating methodologies to assess value across the entire personalization pathway (imaging → design → manufacture → implantation → outcomes)
  - Establishing cost-effectiveness models for distributed vs. centralized production
  - Generating implementation readiness tools for healthcare facilities

- **Objective 2 - Integration of Fragmented Efforts:**
  - Bridging the gap between AM technology developers, healthcare providers, and regulatory bodies
  - Combining expertise from engineering, clinical, economic, and regulatory domains
  - Creating unified evidence standards accepted across sectors

innovative health initiative

Challenges and objectives

- Which unmet public health need are you addressing?

  - **Unmet Public Health Needs Addressed:**
    - **Aging Population with Complex Reconstructive Needs**: Rising demand for personalized orthopedic implants and cranio-maxillofacial reconstructions, need for evidence on outcomes of patient-specific vs. standard implants, and cost-effectiveness data for personalized solutions in elderly populations
    - **Emergency and Trauma Care**: Evidence for on-demand production of surgical guides and implants, assessment of outcomes when devices are produced at point-of-care vs. shipped, and implementation guidance for emergency AM capabilities
    - **Pediatric Populations**: Children require devices that grow/adapt - standard devices often unsuitable and current lack of evidence delays access to personalized treatments

innovative health initiative

Your approach to solve the problem

- BRIDGE-AM aims to establish Europe's first comprehensive real-world evidence ecosystem specifically designed for evaluating personalized medical devices produced through additive manufacturing and their integration into European healthcare system. This 48-month initiative will create a federated network capturing the complete value chain from digital design through point-of-care production to long-term clinical outcomes, addressing the critical evidence gap that prevents widespread adoption of customized medical interventions.

innovative health initiative

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:

A public private collaboration is essential as neither sector alone can address the complexity of evaluating personalized medical manufacturing: while public sector validates clinical utility, private sector ensures technical and economic feasibility.

  - **Public Sector Actors:**
    - Healthcare providers control clinical outcome data and real-world implementation experience
    - Regulatory authorities must co-create evaluation frameworks for batch-of-one devices
    - HTA bodies require involvement from inception to develop acceptable assessment methodologies
    - Academic partners provide methodological independence and scientific validation
  - **Private Sector Actors:**
    - AM manufacturers hold proprietary production parameters and quality metrics essential for evaluation
    - Software companies create workflow integration systems and design algorithms
    - Medical device companies possess regulatory expertise and market access pathways
    - Economic viability assessment requires industry cost and pricing data

- 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)?

  - **Medical Device Sector:**
    - Real-world production data from personalized implants/prosthetics
    - Distributed quality assurance protocols and failure analysis
    - MDR compliance strategies for customization

innovative health initiative

Outcomes and Impact

- What do you expect out of your proposal in terms of concrete results/outcomes and impact?
  - Concrete results include a validated RWE platform processing personalized devices, standardized data collection protocols adopted by European AM centers, open-source evaluation toolkit for personalized medical devices, and regulatory guidance documents endorsed by notified bodies. The general impact include: The accelerated adoption of personalized medical technologies, an evidence base supporting reimbursement of personalized devices and European leadership in regulatory frameworks for distributed medical manufacturing.

- How do you envisage your proposal to ensure translation from research to innovative solutions that can be integrated/implemented into the healthcare ecosystem
  - **Year 1:** Infrastructure establishment in pioneer centers, baseline data collection **Year 2:** Multi-center validation, regulatory sandbox testing **Year 3:** HTA integration pilots, reimbursement framework development **Year 4:** Full deployment, training programs, sustainability transition. This proposals translation success depends on co-development with national HTA agencies from project start, embedded implementation research in hospitals and continuous stakeholder engagement.

- How does your project proposal contribute to strengthening the competitiveness of the Union's health industry?
  - This project enables EU to set global standards for personalized device evaluation and paves the way for European companies capture more share of the $10B+ and growing global AM healthcare market. More SMEs are enabled through validated pathways thus strengthening EU innovation pipeline and reduction in time-to-market for personalized solutions.

- How does your project proposal contribute to the expected benefits for patients?
  - Several studies have shown a reduction in implant failure rates through optimized design, improvement in patient satisfaction scores and decrease in pediatric device wait times, this project would further generate holistic evidence of benefits for patients including access to previously unavailable personalized treatments, pediatric patients receiving growth-adaptive implants and elderly receiving age-appropriate reconstructive solutions.

innovative health initiative

Expertise and resources

- We have:
  - MGA has a network of members in the AM space as mentioned below:
  - Medical AM Specialists + Tier 1 AM Companies: Materialise, Stratasys, Pilot Experience: Hospitals with operational point-of-care manufacturing, Clinical Expertise: Surgeons experienced in patient-specific implants, Research Infrastructure: Biomedical engineering departments with 3D printing labs, Regional Ecosystems: Connected to regional clusters, AM Regulatory consultants: e.g., BeOnQuality, etc, and Standards Bodies: e.g, DIN, amongst others

- We are looking for:
  - Medical Device Companies: e.g Orthopedic: DePuy Synthes, Smith & Nephew Dental/Maxillofacial: e.g. Straumann, KLS Martin, Henry Schein, Notified Bodies: BSI, HTA Agencies: G-BA , HAS etc. Health Economists: Experience in cost-effectiveness analysis and HTA submissions, IP Law Firms: Distributed manufacturing liability experts, Cybersecurity: Specialized firms for distributed manufacturing security, Digital Health Integrators, Payer Organizations: Insurance companies ready to pilot reimbursement models, Clinical Trial Organizations: CROs with medical device trial experience, and Patient Organizations: Long-term care + pediatric advocacy groups, amongst others.

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

innovative health initiative

Additional information

- MGA’s mission is to advance additive manufacturing as a core production method. We bridge the gap between users' needs and suppliers' solutions, open new business opportunities, and represent the industry to political and public institutions. We work to ensure quality across systems, improve processes, develop skilled professionals, strengthen the digital supply chain, and provide legal clarity. We bring together over 140 players from across the AM ecosystem. Our working groups create a hub for collaboration, innovation, and knowledge sharing.

innovative health initiative

Thank You!