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# GENEVA REVIEW

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Expert Perspectives on Responsible  
Artificial Intelligence (AI) in Diabetes Care

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A White Paper • Strategic Roundtable • Global Health Campus, Geneva • 19 September 2025

Chaired by **Prof. Peter Schwarz**, President, International Diabetes Federation (IDF)

Convened by **Dr. Amit Kumar Dey**, Chair, IDF Technology & AI Working Group

Moderated by **Pradeep Kakkattil**, Founder, HIEx

Hosted by **Dure Technologies**

*With the participation of representatives from*

**International Diabetes Federation • WHO • FIND • ITU/FG-AI4H • World Diabetes Foundation • IFRC  
Harvard University • Ex-ICMR • Ethiopian Diabetes Association • VitaFi Denmark • Dure Technologies • HIEx**

R E L E A S E D

**19 May 2026**

Side Event • 79th World Health Assembly • Geneva

## Foreword

*This document is a white paper and expert roundtable review. It summarises the multi-stakeholder deliberations of the Strategic Roundtable on Responsible Use of AI in Diabetes Care, convened by the International Diabetes Federation (IDF) at the Global Health Campus, Geneva, on 19 September 2025. It reflects the collective perspectives, evidence, and policy directions that emerged from that exchange. It does not constitute a formal institutional position of IDF. The roundtable was conducted under Chatham House Rules; accordingly, this document presents institutional positions, evidence, and collective expert recommendations rather than individually attributed views.*

On 19 September 2025, the IDF Technology & AI Working Group convened a Strategic Roundtable on *Responsible Use of Artificial Intelligence in Diabetes Care* at the Global Health Campus in Geneva. The session brought together senior representatives from WHO, FIND, ITU/FG-AI4H, the World Diabetes Foundation, IFRC, Harvard University, Ex-ICMR, national diabetes associations, and technology implementation partners. The foundational consensus that emerged is summarised in this Review.

In the months since the roundtable, the urgency of this agenda has only intensified. The EU AI Act's high-risk provisions for medical devices are on a firm compliance trajectory toward August 2027. India's Central Drugs Standard Control Organisation (CDSCO) has published its first draft guidance on medical device software. The Gates Foundation, Novo Nordisk Foundation, and Wellcome have launched the US\$60 million Evidence for AI in Health (EVAH) Initiative—acknowledging that of 86 randomised controlled trials on AI health tools conducted between 2018 and 2023, only four took place in low- and middle-income countries.<sup>38</sup> And the WHO's template regulatory law for AI in health, announced at the roundtable, is now in advanced preparation.

The IDF Technology & AI Working Group releases this Geneva Review on 19 May 2026 at a side event during the **79th World Health Assembly (WHA)** in Geneva, to contribute to the broader global dialogue on responsible AI in health. The WHA agenda - encompassing the successor WHO Global Strategy on Digital Health for 2028–2033, follow-up to the Fourth UN High-Level Meeting on NCDs, and the operationalisation of WHO's AI regulatory framework - intersects directly with every pillar of this Review.

We invite WHO Member States, delegations to the 79th WHA, and all global health stakeholders to consider the evidence and expert perspectives contained within it. The 589 million people living with diabetes cannot wait for the next policy cycle.

*IDF Technology & AI Working Group*

*May 2026*

## Background and Context

On 19 September 2025, the International Diabetes Federation convened a Strategic Roundtable on *Responsible Use of Artificial Intelligence in Diabetes Care* at the Global Health Campus in Geneva, Switzerland. Hosted by Dure Technologies / HIEx and facilitated by the IDF Technology & AI Working Group, this policy-facing session was a dedicated leg of the IDF Global Consensus process, intentionally foregrounding policy-maker perspectives alongside clinical and technical expertise.

The roundtable brought together senior policy and technical leaders from the World Health Organization (WHO), the Foundation for Innovative New Diagnostics (FIND), the International Telecommunication Union Focus Group on AI for Health (ITU/FG-AI4H), the World Diabetes Foundation (WDF), the International Federation of Red Cross and Red Crescent Societies (IFRC), Harvard University, the former Indian Council of Medical Research (ICMR), the Ethiopian Diabetes Association, VitaFi Denmark, and Dure Technologies.

The global impact of diabetes provides the imperative for this Review. An estimated 589 million adults live with diabetes globally, with projections reaching 853 million by 2050. One in two adults with diabetes remain undiagnosed and four in five live in low- and middle-income countries (LMICs) where the ratio of endocrinologists and diabetes educators to people with diabetes is most acute.<sup>1,2</sup> AI - spanning machine learning, deep learning, natural language processing, and agentic systems - holds transformative potential to bridge this resource gap through continuous glucose monitoring (CGM) analytics, automated insulin delivery, retinopathy screening, risk prediction, and diabetes self-management education.<sup>3,4,5</sup>

However, as the IDF Technology & AI Working Group has cautioned, this is a moment that demands both *action and caution*<sup>6</sup>, action to harness the demonstrable benefits, and caution to ensure that the rapid proliferation of AI tools does not outpace the safeguards needed to protect the people they are meant to serve. The roundtable reached broad consensus that AI must fit into the workflow of patient care - not the other way around - and that the field must commit to a philosophy of responsible and humble AI. Simple, trustworthy, and built to under-promise and over-deliver.

This Review is grounded in the IDF Technology & AI Working Group's established framework of 20 critical need-gaps for responsible AI in diabetes care,<sup>6</sup> the WHO's Ethics and Governance of AI for Health guidance,<sup>7,8</sup> the EU AI Act (Regulation 2024/1689), the IMDRF Good Machine Learning Practice principles,<sup>9</sup> and the deliberations, evidence, and consensus that emerged from the Geneva roundtable and parallel regional consultations. It is organised around seven thematic pillars that condense these need-gaps into expert perspectives and policy directions.

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### P I L L A R I

## Data Foundations and Interoperability

The absence of uniform data standards across diabetes technologies is the single greatest barrier to scalable, trustworthy AI in diabetes care. No universal interoperability standards exist across CGM manufacturers, electronic health records (EHR), insulin pumps, and mobile health applications, creating siloed ecosystems that impede both clinical data sharing and the training of AI models on representative datasets.<sup>3,10</sup> The European Diabetes Forum (EUDF) Delphi consensus roadmap, published in

2025, identified limited adoption of open standards as the primary unmet need for AI-driven clinical decision support in Europe.<sup>11</sup>

The roundtable identified poor data completeness, heavy reliance on paper-based records, and fragmented data-sharing frameworks as critical obstacles to AI deployment, particularly in LMIC settings. Participants proposed that overcoming these barriers requires a combination of incentivisation of data sharing, federated learning methodologies, and blockchain-based provenance to ensure data security and fairness.

The enactment of the European Health Data Space (EHDS, Regulation EU 2025/327) represents a paradigm shift in health data governance, establishing Health Data Access Bodies for secondary use of anonymised health data across all EU Member States.<sup>12</sup> Technical solutions such as FHIR-based transformation pipelines have demonstrated feasibility for real-world clinical data standardisation.<sup>13</sup>

#### EXPERT RECOMMENDATIONS

The roundtable identified the following priorities: adoption of open, FHIR-based interoperability standards for diabetes devices and EHR systems; establishment of minimum data quality benchmarks; and inclusion of calibration reporting alongside discrimination metrics for all diabetes AI models submitted for regulatory approval. Experts further recommended that WHO and FIND co-develop a minimal global diabetes dataset standard as a common reference for AI development and validation across jurisdictions.

## P I L L A R I I

### Equity, Inclusion, and Bias Mitigation

The evidence on algorithmic bias in diabetes AI is unequivocal. A landmark analysis of 141 AI-based diabetes studies found that over 90% failed to report participants' ethnic or racial backgrounds.<sup>14</sup> Training datasets remain overwhelmingly skewed toward well-insured, non-Hispanic White populations in high-income countries, while 80% of people with diabetes live in LMICs where data representation is poorest.<sup>15</sup> The seminal work of Obermeyer and colleagues demonstrated how a widely deployed commercial health algorithm systematically underestimated the needs of Black patients by using healthcare expenditure as a proxy for health needs.<sup>16</sup>

Comprehensive frameworks for algorithmic fairness in medicine have detailed how biases arise at every stage - from data acquisition and genetic variation to labelling variability - and have proposed mitigation through disentanglement, federated learning, and model explainability.<sup>15</sup> The FDA-informed Total Product Lifecycle framework provides a structured approach to identifying, measuring, and mitigating bias at every phase of AI development.<sup>17</sup> A five-phase lifecycle approach demonstrates that algorithmic bias is neither inevitable nor merely a technical artefact.<sup>18</sup>

The roundtable recognised that top-down approaches to equity will not succeed and that a common baseline of digital literacy is a prerequisite for equitable AI deployment. Participants from low-resource settings emphasised that foundational data pipelines must be established before AI tools can be meaningfully

deployed, and that persistent language barriers require AI tools to accommodate linguistic and cultural diversity from the outset.

#### EXPERT RECOMMENDATIONS

Mandatory disaggregated performance reporting across race, ethnicity, gender, age, and socioeconomic subgroups should be required for all diabetes AI devices seeking regulatory approval. Lifecycle bias frameworks<sup>18</sup> should be adopted as a global standard, with training dataset composition transparency required in all regulatory submissions. No AI tool for diabetes should receive market authorisation without demonstrated performance equity across the populations it is intended to serve.

### PILLAR III

## Transparency, Explainability, and Calibrated Trust

Trust in AI is not binary; it must be calibrated. A 2024 systematic review found that explainable AI (XAI) approaches can both increase and decrease clinician trust - excessive trust in incorrect AI advice is as harmful as distrust of correct advice.<sup>19</sup> The WHO's January 2024 guidance on large multimodal models explicitly warns against automation bias.<sup>8</sup> The goal is to optimise trust rather than maximise it.

The evidence on large language models (LLMs) in diabetes reveals both promise and limitation. Retrieval-augmented generation frameworks have improved LLM accuracy on diabetes education questions from 72–91% to 91–98%.<sup>20</sup> Yet LLMs still fall short of specialist clinicians in navigating drug accessibility, cost, and metabolic risk considerations.<sup>5</sup> The roundtable observed that AI must be directed to the right clinical challenges, and that genuine patient-centredness requires the patient to drive how AI serves them.

The EU AI Act codifies transparency requirements for high-risk AI systems under Articles 13 and 14.<sup>21,22</sup> The NIST AI Risk Management Framework complements this with seven characteristics of trustworthy AI.<sup>23</sup>

#### EXPERT RECOMMENDATIONS

Risk-stratified transparency requirements should be adopted: autonomous AI systems should provide full explainability, while decision-support tools should provide interpretable confidence levels. Retrieval-augmented generation or equivalent safeguard frameworks should be mandatory for all patient-facing LLM applications. The human-on-the-loop model is recommended for continuous monitoring systems.

### PILLAR IV

## Regulatory Harmonisation and Governance

The regulatory landscape for AI-enabled diabetes devices is converging but remains fragmented. The EU AI Act classifies most AI-enabled diabetes devices as high-risk AI systems, with full compliance obligations becoming

applicable by August 2027.<sup>21,22</sup> The US FDA's PCCP guidance allows pre-specified algorithm modifications within approved safety boundaries.<sup>24</sup> The IMDRF's GMLP document establishes 10 guiding principles.<sup>9</sup>

The roundtable heard that regulatory approval obstacles remain a critical bottleneck. A WHO template regulatory law for AI in health is in advanced development. India's CDSCO published draft guidance on Medical Device Software in October 2025.<sup>25</sup> Policymaker resistance—paralleling early scepticism toward innovations such as HIV self-testing—must be addressed through sustained evidence-based advocacy.

WHO published regulatory considerations for AI in health in October 2023.<sup>26</sup> A 2024 analysis confirmed all major jurisdictions now reference IMDRF and ISO/IEC standards as the basis for convergence.<sup>27</sup>

#### EXPERT RECOMMENDATIONS

Mutual recognition pathways based on IMDRF GMLP principles should be established. WHO should consider a prequalification programme for AI diabetes devices analogous to its TB CAD framework through FIND. The proposed steering committee should develop a unified implementation roadmap.

## P I L L A R V

### Patient Empowerment and Participatory Design

AI tools developed without community engagement risk exacerbating the inequities they claim to address. Only 21 of over 10,000 articles on AI in health mentioned community involvement.<sup>28</sup> The AI4DPP project provides the most developed diabetes-specific participatory framework.<sup>29,30</sup>

The Onelmpact platform, developed by Stop TB Partnership with Dure Technologies, demonstrates how community-led monitoring can be adapted for chronic disease management across more than 10 countries.<sup>31</sup> A next-generation version incorporating voice-enabled conversational AI was unveiled in 2025.

The roundtable reached strong consensus that the patient must be positioned as the leader in technology adoption, and that scale must emerge from community needs rather than being imposed from above.

#### EXPERT RECOMMENDATIONS

Patient and community advisory mechanisms should be established for all diabetes AI tools seeking regulatory approval. Community engagement documentation should be required in regulatory submissions, following the AI4DPP framework.<sup>29</sup> The roundtable affirmed the vision of equitable care facilities with AI placed in the hands of the patient.

## P I L L A R V I

### Infrastructure, Access, and Scalability

The digital divide is profound. Only 27% of low-income country populations use the internet versus 93% in high-income countries.<sup>32</sup> Africa has less than 1% of global data centre capacity. Internet costs in parts of Africa reach 20–30% of average monthly income.<sup>33</sup> A systematic scoping review found only 10 qualifying real-world AI implementations in LMICs.<sup>34</sup>

Yet feasibility is demonstrated. Offline-first AI applications deliver diagnostic-grade results on devices with 1 GB memory without connectivity.<sup>35</sup> Federated learning has decreased data breach risk by 40% while improving outcomes by 15%.<sup>36,37</sup>

The roundtable identified that foundational infrastructure gaps—including electricity and connectivity—must be addressed. The US\$60 million EVAH Initiative directly addresses the LMIC evidence gap.<sup>38</sup>

#### EXPERT RECOMMENDATIONS

Offline-first, edge-computing AI solutions should be prioritised for LMIC deployment. Global federated learning consortia should be established. AI developers should demonstrate context-specific cost-effectiveness, and dedicated digital infrastructure investment should be recognised as a prerequisite for equitable AI adoption.

## P I L L A R V I I

### Monitoring, Evidence, and Lifecycle Accountability

Post-market surveillance is inadequate. Only 943 adverse event reports were filed for ~950 AI/ML devices (2010–2023).<sup>39</sup> Only 20.5% of 691 FDA-cleared AI/ML devices provided risk statements, only 1.9% included published validation.<sup>40</sup>

Time in Range (TIR, 70–180 mg/dL) has been validated as a clinical trial endpoint.<sup>41</sup> Real-world data from over 100,000 AID users demonstrated sustained TIR of 78% over three years.<sup>42</sup> Three AI-specific reporting guidelines exist—CONSORT-AI, SPIRIT-AI, and TRIPOD+AI<sup>43,44,45</sup>—yet adherence remains inconsistent. The concept of “algorithmovigilance” has been proposed.<sup>39</sup>

#### EXPERT RECOMMENDATIONS

An international AI diabetes device registry should be established. Adherence to CONSORT-AI, SPIRIT-AI, and TRIPOD+AI should be expected for publicly funded research. An AI-specific HTA pathway and “algorithmovigilance” protocols should be developed.

## Emerging Directions and Next Steps

The Geneva roundtable identified forward-looking priorities:

**Multi-stakeholder steering committee.** A steering committee bringing together multilateral agencies, national regulatory authorities, clinical and technical experts, civil society, and people living with diabetes was proposed to ensure all stakeholder voices are reflected in an implementation policy brief and roadmap.

**Synthesis and consensus development.** The IDF Technology & AI Working Group is developing a comprehensive synthesis to feed into the IDF Global Consensus process through subsequent Delphi rounds.

**Thematic working groups.** Working groups along each pillar are envisioned to develop technical standards, policy recommendations, and implementation toolkits.

**Contribution to global policy processes.** This Review is offered as a contribution to the 79th WHA deliberations, relevant to: (a) the successor WHO Global Strategy on Digital Health; (b) regulatory harmonisation for AI-enabled health technologies; (c) post-market surveillance standards; (d) digital infrastructure investment within UHC frameworks; and (e) a potential WHO prequalification programme for AI health devices.

Alignment with the Fourth UN High-Level Meeting on NCDs and the UN Global Dialogue on AI Governance is also recommended.

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## Concluding Perspectives

The 589 million people living with diabetes deserve nothing less than AI technologies that are safe, equitable, transparent, and accountable. The convergence of the EU AI Act, FDA lifecycle frameworks, IMDRF GMLP principles, emerging national AI health strategies, and the forthcoming WHO template regulatory law creates a decisive window for global harmonisation.

**The experts assembled in Geneva chose convergence. They chose the person. They chose responsible and humble AI that under-promises and over-delivers.**

This Review is offered to the wider IDF membership, WHO Member States, global health stakeholders, and the diabetes community as a resource for informed deliberation and action. The IDF Technology & AI Working Group will continue to develop the formal IDF Consensus on Responsible AI in Diabetes Care through its established scientific and consultative processes.

*Deliberated at Geneva, Switzerland, 19 September 2025*

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