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An Implementation Supportive Framework for context-sensitive health technology adoption: international expert validation using biosimilars

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Scope Statement

Using biosimilars as an illustrative pharmacological case, our study investigates the interface between health technology assessment, drug policy, and implementation planning. It reports an international qualitative expert workshop that assesses and refines a technology-agnostic Implementation Supportive Framework (ISF) designed to guide context-sensitive adoption and sustained use of pharmacological technologies. By analysing how governance arrangements, financing flows, industrial policy, cultural acceptance, and distributional context shape feasible implementation pathways for biosimilars, the manuscript contributes empirically grounded, decision-oriented insights into how drugs perform beyond regulatory approval and reimbursement decisions. The findings directly support the specialty's aims by providing a structured approach for linking evidence appraisal with real-world drug outcomes and policies, thereby informing more effective, efficient, and equitable implementation of biosimilars and other complex therapies across diverse health systems.

Conflict of interest statement

The authors declare a potential conflict of interest and state it below

The author(s) declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision

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Keywords

biosimilar implementation, context-sensitive decision-support, governance and financing context, Health Technology Assessment, Implementation planning, Implementation Supportive Framework

Abstract

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Introduction: Evidence–implementation gaps in health technologies persist across health systems, even where clinical and economic evidence is well established, partly because implementation planning does not systematically account for governance, financing, and sociocultural context. This study aimed to assess the conceptual robustness and perceived applicability of a technology-agnostic Implementation Supportive Framework (ISF) for implementation planning as a context-sensitive decision architecture at the interface between health technology assessment (HTA), evidence generation, and implementation, using biosimilar implementation as an illustrative case. Materials and methods: A qualitative international expert workshop was convened with senior stakeholders from ministries, regulatory and HTA bodies, payer organisations, clinical practice, and implementation research. The ISF served as the central discussion framework and was applied to a biosimilar implementation case in moderated small-group discussions followed by plenary synthesis. Discussions were documented through structured notes and analysed using descriptive thematic analysis aligned with predefined research questions and implementation outcomes, including acceptability, appropriateness, and structural completeness as a framework-level characteristic. Results: Experts regarded the ISF as a coherent high-level architecture for linking evidence appraisal, contextual analysis, and implementation pathway selection, but identified gaps in the representation of governance arrangements, financing flows, industrial policy, and cultural acceptance and trust. Modelling approaches, including decision trees, Markov models, microsimulation, system dynamics, and logic models, were valued mainly as tools to structure assumptions and make trade-offs transparent rather than to identify a single optimal strategy. Discussion: Four priority adaptations were proposed: explicit governance-mapping tools, more detailed depiction of financing flows and budget-holding responsibilities, operational indicators for cultural acceptance and trust, and a more modular, selectively activable ISF architecture. A framework that systematically incorporates these contextual dimensions may better support context-sensitive selection and adaptation of implementation pathways for a range of health technologies, with biosimilars illustrating how the ISF could inform decision-making at the evidence generation–implementation interface.

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An Implementation Supportive Framework for context-sensitive health technology adoption: international expert validation using biosimilars

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Abstract

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Keywords: Implementation Supportive Framework; implementation planning; health technology assessment; governance and financing context; biosimilar implementation; context-sensitive decision-support

1 Introduction

The translation of evidence into routine decisions in healthcare and into actual technology use, varies across health systems [1]. Significant time lags between discovery and widespread use in practice have been documented, though their extent varies markedly across technologies and settings [2, 3]. Regulatory approvals and reimbursement decisions, including those informed by established health technology assessment (HTA) processes, do not on their own guarantee adoption, sustained use or system-wide integration of health technologies [4-6]. Implementation processes are shaped by institutional structures, governance arrangements, financing mechanisms, professional cultures, and stakeholder interactions [7].

Implementation research has shown that adoption and sustainment are context dependent [8]. Determinant frameworks such as CFIR identify factors that shape implementation outcomes [9]. However, these frameworks have primarily been used to analyse and evaluate implementation retrospectively rather than to structure implementation decisions prospectively [10]. As a result, implementation research offers rich descriptions of contextual influences but comparatively less actionable guidance on how decision-makers should systematically select and organise implementation strategies before roll-out [11].

In parallel, HTA processes focus on value assessment across clinical, economic, ethical, legal, social, environmental, and organisational aspects [12]. In most health systems, HTA is mainly used to inform reimbursement and coverage decisions rather than to plan, structure, or guide the implementation of approved technologies. As a consequence, there is typically no dedicated, framework-based process for selecting and adapting implementation pathways to specific institutional and health-system contexts. This functional separation between technology evaluation and implementation planning framework may contribute to persistent evidence–implementation gaps, particularly where governance, financing and sociocultural conditions differ markedly within and across countries [7].

International discussions on implementation have emphasised contextual determinants beyond scientific evidence, including stakeholder acceptance, institutional readiness and alignment with governance and financing arrangements [13]. These discussions informed the development of an Implementation Supportive Framework (ISF), conceived as a modular, technology-agnostic decision-support architecture linking evidence appraisal, contextual analysis, pathway selection and sustainability planning. Rather than functioning as a prescriptive implementation model, the ISF is intended to support decision-makers in selecting and adapting implementation strategies according to contextual characteristics within different health systems. The ISF is organised into broad contextual domains (for example governance, financing, culture and distributional context) and more specific contextual dimensions, such as who holds decision authority, how budgets and payments are structured, or how trust in a technology is shaped (Supplementary material 1). This study aimed to assess the conceptual robustness and potential global applicability of the ISF across diverse health-system contexts. The study addressed four questions:

1. RQ1: To what extent does the ISF capture relevant contextual domains and their associated dimensions across heterogeneous health systems?
2. RQ2: Are there any contextual domains that are under-represented in the current ISF specification? If so, which domains and dimensions are insufficiently captured?
3. RQ3: What mechanisms within ISF support adaptive, context sensitive selection of implementation pathways?
4. RQ4: Which structural modifications to ISF are required to enhance its applicability across different health systems embracing governance and financing arrangements?

2 Materials and Methods

2.1 Study design

A qualitative international expert workshop was conducted. Reporting of qualitative methods was informed by the COREQ checklist where applicable. It was recognised that the workshop format did not fully align with interview- or focus-group-based designs because data were generated through moderated roundtable discussions, plenary exchanges and open cross-country debate rather than through individual interviews or formally structured focus groups [14]. The implementation issue examined in the workshop concerned health technologies, while the ISF was the framework under assessment.

No formal ethics committee approval was sought because the workshop involved professional experts acting in their institutional roles, did not collect personal or patient-level health data, and focused on policy- and system-level reflections. Participation was voluntary, and contributors were informed that anonymised, aggregated summaries of the discussions might be used for scientific publication. No individual or institutional identifiers were reported. To enhance transparency, the analysis plan were documented in an Open Science Framework registration (https://osf.io/e3ytw).

2.2 Rationale for workshop design

Earlier workshops had outlined the core components of the ISF and its potential to link HTA outcomes with implementation planning, but had not examined how the framework would be interpreted across diverse health systems and contextual configurations [15, 16]. The present workshop therefore sought structured feedback from experienced decision-makers on whether the ISF was conceptually robust and practically useful for guiding implementation decisions across heterogeneous governance and financing settings.

Following Proctor and colleagues' terminology, the workshop focused on two primary implementation outcomes: the acceptability of the ISF as a decision-support framework and its perceived appropriateness for capturing governance, financing, and cultural determinants of implementation [17]. In addition, structural completeness was introduced as a framework-level characteristic, defined as the extent to which relevant contextual domains and decision steps are represented within the ISF. These outcomes and framework characteristics informed both the workshop design and the subsequent qualitative analysis [18].

2.3 Participant selection

Participants were selected using purposive sampling based on their roles in reimbursement, regulation, or implementation of health technologies and their involvement in international forums on implementation. Invitations were distributed directly and through professional networks to ensure regional, gender and professional diversity.

2.4 Health-system and policy context

The workshop was designed to include experts from health systems with different governance and financing arrangements, specifically tax-funded national health services, social health insurance systems and mixed public–private models across Latin America, Europe, the Middle East and Asia [19, 20]. In selecting participating countries, attention was paid to variation in the degree of centralisation, ranging from systems in which national authorities hold primary responsibility for pricing and reimbursement decisions to those in which substantial authority is delegated to regional purchasers or insurers [21-23]. This planned heterogeneity in health-system characteristics provided the context for exploring how the ISF might be applied and adapted across settings.

2.5 Case application Biosimilars

Biosimilars were selected as the illustrative implementation case. Regulatory frameworks for biosimilars are broadly aligned with World Health Organization and European Medicines Agency standards, yet reimbursement functions, budget-holding responsibilities, provider payment mechanisms, and uptake patterns vary markedly between settings [24-26]. Previous work has also shown that pricing, procurement, trust, and local policy conditions shape biosimilar implementation. Together, these characteristics made biosimilars a suitable case for examining how the ISF captures governance, financing, and cultural determinants of implementation [27-30].

2.6 Setting and workshop procedure

The workshop was conducted as a one-day, in-person meeting comprising plenary and breakout sessions and was framed as a forum for cross-country exchange on context-sensitive implementation of health technologies. The workshop procedure consisted of four components in sequence: an introduction to the core ISF modules, regional presentations on governance, financing, and regulatory arrangements for biosimilars, roundtable discussions applying selected ISF modules to the biosimilar case, and plenary synthesis of proposed implementation pathways and priorities for further refinement.

Roundtable discussions were moderated by facilitators from different geographical regions and professional backgrounds. Country representatives described their national contexts and outlined possible implementation pathways for biosimilars using the ISF modules, indicating where additional components would be required. Plenary sessions synthesised similarities and differences across systems and enabled participants to verify, correct, and nuance recorded interpretations before analysis.

2.7 Data collection and analysis

Roundtable discussions were documented using structured flipchart notes and consolidated during plenary sessions into a single workshop protocol. An exploratory qualitative thematic analysis was conducted in three stages. First, the consolidated notes were read repeatedly to familiarise the researcher with the material and to map the content to the four research questions. Second, the notes were sorted using a combination of a priori categories and the implementation outcomes of acceptability, appropriateness, and structural completeness, supplemented by emerging themes. Third, topics were grouped into higher-level themes and mapped back to the research questions and ISF modules to develop a narrative synthesis of convergence and divergence across health systems. The thematic structure was reviewed by co-authors with expertise in HTA and implementation science.

3 Results

A total of 28 participants took part, including representatives from HTA agencies and payer organisations (n = 12), regulatory authorities (n = 6), academic institutions (n = 9), and clinical practice (n = 1). Participants represented health systems from Austria, Belgium, Brazil, Chile, Colombia, Egypt, Germany, Hong Kong, Ireland, Malaysia, Saudi Arabia, Spain, Thailand, and Türkiye.

3.1 Governance configuration and structural completeness of the ISF

In relation to RQ1, participants generally regarded the ISF as structurally complete at a high level, in the sense that it provides a coherent architecture for linking evidence appraisal with implementation planning. At the same time, they highlighted that the current specification remains insufficiently explicit with respect to governance diversity, particularly where decision authority extends beyond HTA-supported appraisal to ministries, budget holders or subnational actors. Across countries, participants described marked variation in the location of decision authority, the role of payers, and the extent of centralisation. These governance configurations were not seen as peripheral contextual details, but as structural features that determine which implementation pathways are feasible, who can activate them, and where veto points may arise, and thus as critical determinants of the structural completeness of the ISF in practice.

3.2 Underrepresented contextual domains

Addressing RQ2, participants identified four contextual domains as insufficiently represented in the current ISF specification: industrial policy, financing, cultural acceptance and trust, and distributional context. Figure 1 shows how these domains relate to the core ISF modules and where participants considered additional contextual specification necessary.

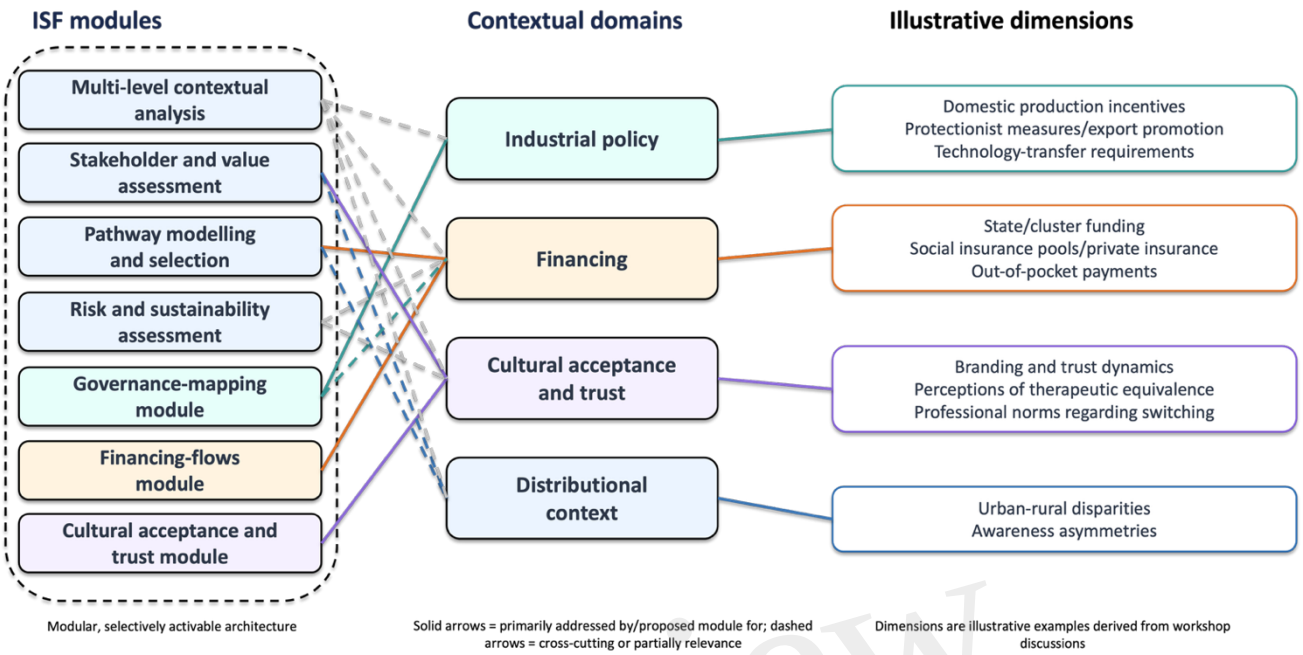

Figure 1. Mapping of ISF modules to contextual domains and dimensions identified in the workshop

Industrial policy was described as relevant where implementation is shaped by domestic production incentives, protectionist measures, export promotion, or technology-transfer requirements. Participants emphasised that such factors may influence adoption decisions independently of clinical evidence or cost-effectiveness and therefore affect the practical choice of implementation pathways within the ISF.

Financing was discussed not only in terms of reimbursement decisions, but also in relation to who holds budgets, how funds flow through the system, and which actors bear financial risk. State or cluster funding, social insurance pools, private insurance, and out-of-pocket payments were seen as generating different incentive structures, which in turn shape whether implementation strategies are likely to be attractive, feasible, or sustainable.

Cultural acceptance and trust included branding effects, perceptions of therapeutic equivalence, confidence in supply continuity, brand preference, and professional norms regarding switching. Participants regarded these issues as central to implementation because they influence uptake behaviour directly, yet they considered them only weakly operationalised in the present ISF.

Distributional context referred to differences in access, awareness, and exposure across settings, including urban-rural disparities and asymmetries in provider or patient familiarity with biosimilars. These factors were considered relevant because they affect whether a given implementation pathway can be applied uniformly or requires adaptation across service environments.

Error! Reference source not found. summarises the four underrepresented domains, the main contextual dimensions identified in the workshop, and their implications for implementation pathway selection within the ISF.

Table 1. Underrepresented contextual domains and their implications for the ISF

Under-represented Domain	Key contextual dimensions identified in the workshop	Implications for implementation pathway selection
Industrial policy	Domestic production incentives; protectionist measures; export promotion; technology-transfer requirements	Shape implementation independently of evidence or cost-effectiveness.
Financing	State or cluster funding; social insurance pools; private insurance; out-of-pocket payments	Generate distinct incentive structures for biosimilar use
Cultural acceptance and trust	Branding effects; perceptions of therapeutic equivalence; supply confidence; brand preference; professional norms regarding switching	Influences uptake behaviour directly and requires explicit consideration in pathway design, communication, and implementation sequencing.
Distributional context	Urban-rural disparities; awareness asymmetries; uneven provider and patient exposure	Affects whether implementation pathways are feasible across all settings or need local adaptation.

3.3 Mechanisms supporting context-sensitive pathway selection

For RQ3, participants were asked to identify mechanisms within the ISF that support the context-sensitive selection of implementation pathways. Across groups, modelling approaches such as decision trees, Markov models, microsimulation, system dynamics, and logic models emerged as the most consistently discussed mechanism. However, these were not primarily valued as tools for identifying a single optimal strategy; rather, they were seen as tools for making assumptions, actor relationships, resource flows, and trade-offs explicit.

Participants distinguished between descriptive uses of modelling, such as mapping governance, financing, and utilisation patterns, and prescriptive uses, such as comparing feasible implementation pathways under specified constraints (e.g., budget limits, regulatory requirements, or capacity). In this sense, modelling was viewed as a mechanism that could help operationalise contextual analysis within the ISF by connecting governance mapping and financing structures to concrete pathway choices.

Participants also noted that such modelling capacity would likely be more feasible at national or regional policy level than at the level of individual providers. This reinforced the view that the ISF is best positioned as a strategic decision-support architecture for meso- and macro-level implementation planning.

3.4 Required structural adaptations of the ISF

In response to RQ4, workshop discussions converged on four priority structural adaptations to the ISF. These adaptations translate the contextual domains highlighted above into specific framework requirements rather than leaving them as general background considerations. Table 2 presents these four priority adaptations and their intended function within the ISF.

Table 2. Priority structural adaptations of the Implementation Supportive Framework (ISF)

Domain	Priority adaptation of ISF	Description
Governance	Governance-mapping module	Explicit mapping of decision-making bodies, veto points and accountability lines.
Financing	Detailed representation of financing flows and budget holders	Differentiation of public, social insurance and private payment structures.
Culture	Cultural acceptance and trust module	Indicators on stakeholder trust, branding, communication and procurement history.
System heterogeneity	Modular, selectively activable ISF architecture	Modules that can be turned on/off depending on health-system configuration.

First, participants proposed an explicit governance-mapping component to identify decision-making bodies, veto points, and lines of accountability. Second, they called for more detailed representation of financing flows and budget-holding responsibilities. Third, they highlighted the need for a cultural acceptance and trust component that captures stakeholder perceptions, communication needs, and behavioural barriers to uptake. Fourth, they proposed a more modular ISF architecture, allowing components to be activated selectively depending on health-system configuration and analytical capacity.

4 Discussion

This study makes three contributions to the field. First, it provides an international, multi-stakeholder assessment of the conceptual robustness of the ISF as a prospective implementation planning tool. Second, it identifies four specific contextual domains that the current ISF specification does not yet capture sufficiently. Third, it proposes concrete structural adaptations that translate these gaps into actionable framework components. Each of these contributions is discussed below in relation to the existing literature.

Participants regarded the ISF as acceptable as a high-level decision-support architecture. This finding is consistent with broader arguments in implementation science that frameworks must be perceived as relevant and usable by the practitioners who apply them. Moullin et al. emphasised that frameworks are most effective when selected based on their fit to the specific implementation phase and context [31]. The ISF was designed for this purpose. To support prospective rather than retrospective implementation planning. The positive assessment of acceptability from a diverse international expert

group therefore provides initial evidence that the ISF addresses a gap that existing frameworks have left open [10, 11]

A recurring theme in the workshop was the absence of structured, pre-implementation guidance for selecting contextually appropriate pathways. This reflects a limitation that Nilsen has described at a taxonomic level: determinant frameworks such as CFIR were developed primarily to explain and analyse implementation outcomes, not to guide prospective decision-making [10]. As Moullin et al. also noted, frameworks are often applied too late in the implementation process to shape the critical choices made at the planning stage The ISF is intended to address this by positioning contextual analysis upstream, before pathways are selected [31]. The present study suggests that this positioning is regarded as appropriate by experienced decision-makers from diverse health systems.

The most consistently raised concern was the insufficient representation of governance complexity within the ISF. Participants described substantial variation in decision authority, from systems with integrated ministerial control to highly decentralised models with regional purchasers and multiple veto points. These observations align with the updated CFIR 2.0, in which Damschroder et al. expanded the Outer Setting domain to include policy environments, equity considerations, and external governance pressures [32]. Similarly, the CICI framework developed by Pfadenhauer et al. distinguishes political and legal domains as distinct context dimensions that can shape implementation independently of clinical evidence [13]. The ISF's current specification treats governance primarily as background rather than as a structured analytical domain. A dedicated governance-mapping component, as proposed by workshop participants, would bring the ISF into alignment with these broader arguments for making governance explicit in implementation planning.

Participants also identified financing as underrepresented, noting that the current ISF does not differentiate between public budgets, social insurance pools, private insurance, and out-of-pocket payments. These distinctions matter because they shape incentive structures, budget responsibilities, and the feasibility of specific implementation strategies. This finding echoes work on biosimilar uptake variability, which has consistently shown that pricing and reimbursement architectures are among the strongest determinants of adoption patterns across countries [27, 30]. A more granular representation of financing flows within the ISF would allow users to link contextual analysis more directly to the selection of pathway options.

Cultural acceptance and trust were identified as central to implementation but operationally underdeveloped in the current ISF. Participants discussed branding effects, perceptions of therapeutic equivalence, and professional switching norms as factors that influence uptake independently of regulatory or reimbursement decisions. The CICI framework addresses sociocultural context as one of its seven context domains. However, as Pfadenhauer et al. noted, operationalising sociocultural factors in a way that is actionable for implementation planners remains a challenge [13]. The workshop findings suggest that, for the ISF, operationalisation should focus on indicators that are directly relevant to pathway choice: trust levels among prescribers, patient familiarity with biosimilars, and historical procurement patterns.

The finding that modelling approaches are valued primarily as communication tools rather than optimisation instruments has practical implications. It suggests that the role of quantitative models within the ISF is not to determine a single best pathway, but to make assumptions, resource flows, and trade-offs transparent for multi-stakeholder discussions. This use of modelling fits with what Moullin et al. described as the facilitation function of implementation frameworks: supporting shared understanding among actors with different knowledge bases and incentives [31]. It also implies that

the modelling components of the ISF should be designed to be accessible to users with limited analytical capacity, which is consistent with the call for a more modular and selectively activable ISF architecture.

From a practical standpoint, the proposed ISF adaptations suggest a clear direction for further development. HTA agencies and implementation-planas ning bodies could use the ISF as a structured pre-implementation tool, activating governance-mapping, financing-flow, and cultural-acceptance modules before pathway selection begins. This would fill the gap that Segar et al. identified: the absence of operationalised guidance for turning HTA recommendations into context-specific implementation strategies [11]. The modular architecture proposed by workshop participants would allow organisations with limited analytical capacity to engage with the ISF incrementally, a design principle that Moullin et al. also highlighted as important for real-world framework uptake [31].

The study has multiple strengths. It drew on an international, multi-stakeholder sample across 14 countries and health-system types, and it used iterative plenary synthesis to validate interpretations. At the same time, several limitations should be acknowledged. The study is based on expert judgement rather than empirical measurement of implementation outcomes. It relies on a single technology case, and the one-day workshop format constrained the depth of exploration for all ISF components. Future research should prospectively test the adapted ISF in other technology domains, validate the proposed adaptations with quantitative or mixed-methods approaches, and develop practical decision-support tools for governance mapping, financing analysis, and cultural assessment. The adapted Implementation Supportive Framework therefore offers a practical, conceptually grounded tool to link health technology assessment with context-sensitive implementation planning for biosimilars and other health technologies.

5 Statements

5.1 Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

5.2 Author Contributions

Maximilian Otte: Investigation, visualization, funding acquisition, writing – original draft, writing – review and editing, data curation, formal analysis, methodology, conceptualization, and project administration. Hussain Abdulrahman Al-Omar: Validation and writing – review and editing. Elena Guillen: Validation and writing – review and editing. Yan Nee Gan: Validation and writing – review and editing. Iñaki Gutiérrez-Ibarluzea: Validation and writing – review and editing. Gökhan Ertaylan: Validation and writing – review and editing. Beate Jahn: Validation and writing – review and editing. Nitichen Kittiratchakool: Validation and writing – review and editing. Deirdre Mullen: Validation and writing – review and editing. Augusto Afonso Guerra Junior: Validation and writing – review and editing. Hans-Peter Dauben: Methodology, conceptualization, validation, supervision, funding acquisition, formal analysis, and writing – review and editing.

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5.5 Data availability statement

The datasets generated and analysed during the current study consist of anonymised workshop notes. They are not publicly available in order to protect participant confidentiality under the Chatham House Rule, but are available from the corresponding author on reasonable request and subject to applicable institutional and data-protection requirements.

5.6 Ethics statement

The workshop involved professional experts acting in their institutional roles and did not collect or analyse identifiable personal or patient-level data. Participation was voluntary, and contributors were informed that anonymised, aggregated summaries of the discussions might be used for scientific publication. In accordance with local legislation and institutional requirements, formal ethics committee approval and written informed consent were not required.

5.7 Generative AI statement

Perplexity (Perplexity AI, model GPT-5.1) was used during the final sanity check of the manuscript for language polishing and consistency checking. All content was critically reviewed and approved by the authors, who remain responsible for the accuracy and integrity of the work.

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