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Position Article

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Translational bioinformatics stalls at implementation

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Abstract

Bioinformatics tools are increasingly important for diagnostics in clinical care and precision medicine, but despite a very active bioinformatics research community, implementation and adaptation is slow. Drawing on multidisciplinary expertise, we have identified key systemic barriers on the journey from research to implementation, using the Danish healthcare ecosystem as the example. We find the main obstacles to be regulatory uncertainty, fragmented data access, and limited infrastructure for implementation. Cultural resistance to commercialization and workforce gaps further impedes progress. We believe that these challenges reflect broader international trends and could be generally applicable. Consensus recommendations include centralized data and regulatory resources, cross-sector collaboration models, and pilot initiatives to support scalable implementation. These findings offer a roadmap for translating bioinformatics innovation into clinical practice.

Keywords clinical bioinformatics, implementation, translational bioinformatics, bioinformatics research, resource management

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Introduction

Despite the growing importance of bioinformatics in clinical diagnostics and precision medicine, implementation remains inconsistent, fragmented, and with only very small incremental advancements over the two decades [1, 2], a challenge that mirrors the well-described "research-to-practice gap" in medicine more broadly [3]. The translation is essential because most existing software and infrastructure spring from academic research—or its commercial offshoots—and often fail to align fully with clinical requirements and workflows [4]. Prior to the initiative presented here, understanding of implementation challenges was largely anecdotal and locally framed, limiting the ability to address systemic issues as a community [5].

To address this gap, we conducted a structured workshop with experts across clinical, academic, regulatory, and administrative domains. Through a pre-meeting questionnaire and 2 days of moderated discussion, we identified shared challenges and areas of consensus and opposing views. Participants represented a mix of clinical, academic, legal, and IT domains. Key obstacles were identified to be insufficient knowledge of regulatory requirements, poor data accessibility, unclear criteria for success, and structural barriers to commercial adoption. This white paper synthesizes these insights, aiming to provide a foundation for coordinated efforts to translate bioinformatics innovations into clinical practice in the Danish healthcare system.

Materials and methods

We constructed a questionnaire with 19 questions to be answered anonymously (Supplementary File S1). The questions were a mix of multiple choice questions (with possibility to add additional answer options and elaborate on the selected answer) and free-text response questions. Of the 23 survey respondents (88% response rate), self-identified roles included two medical doctors, two legal or regulatory professionals, and two in clinical decision support (non-MD, non-bioinformaticians). Eight identified as clinical bioinformaticians, five of whom also reported academic affiliations. Five respondents identified primarily as academic bioinformaticians, including two with subspecialties in metabolomics and translational medicine, and two with additional involvement in business or entrepreneurship. Three respondents work in clinical advisory or medical IT operations.

The workshop was conducted in person over 2 days and included 28 participants. The format combined short presentations exemplifying implementation challenges with moderated discussions, breakout group sessions, and plenary debates. Participants were primed through the pre-meeting questionnaire and were invited to engage actively in discussions. Breakout groups were assembled randomly to promote cross-disciplinary exchange. Outputs were synthesized through structured gap analyses during breakout sessions and summary reports presented by session chairs in the plenary.

Results

Lost in regulation: Most researchers don't know the rules for bringing bioinformatics inventions into the clinic

Despite the increasing clinical relevance of bioinformatics, most researchers lack a clear understanding of regulatory pathways. In our survey, 78.3% of respondents were unsure about the requirements for implementing bioinformatics tools in hospitals, including accreditation, validation, and legal compliance. This uncertainty delays the transition from prototype to clinical production, not the least because it creates a mental barrier even though there might be no practical barrier.

To address this, participants emphasized the need for practical guidance and institutional support. Proposed solutions include a centralized knowledge base, standardized regulatory templates, and automated validation tools. Strengthening collaboration between developers, IT teams, and regulatory experts, as well as targeted training for all stakeholders, was identified as key to integrating compliance into development from the outset. Respondents specifically highlighted skill gaps in regulatory and compliance expertise, data governance, and understanding of clinical workflows, suggesting that current workforce development efforts may not sufficiently support translational goals. There was a consensus that not all experts involved in all steps of translational bioinformatics research need to become experts in regulation and implementation requirements, but that introductory courses at university level as well as available guidelines about regulatory frameworks would lower the perceived barrier. Dedicated legal or compliance experts embedded in hospital research units could expedite approvals by interpreting legislation and assisting with documentation.

Data access barriers stall clinical bioinformatics—And centralization is the way forward

Access to high-quality, well-annotated and documented clinical data are essential for developing and validating bioinformatics tools. Yet, over 75% of respondents cited inconsistent data availability, non-standardized formats, legal and ethical constraints, and poor metadata documentation as key barriers to reusing existing data.

Data access remains especially fragmented for niche datasets and smaller cohorts, where availability often depends on local data stewards and ad hoc approval processes. While local oversight offers close domain knowledge and curated metadata, the lack of standardization and reliance on individual gatekeepers creates bottlenecks.

Participants expressed strong support for a shift toward centralized data repositories (100% of the respondents), such as the Danish National Genome Center, provided they offer transparent metadata summaries prior to access. To improve data usability, respondents recommended national mandates for data deposition, standardized documentation practices, and searchable inventories and centralized active data stewardship. There was unanimous agreement that structural enforcement—not just voluntary incentives—is needed to ensure data accessibility, while maintaining legal and ethical safeguards. The opposing view that data management must be at the level of the data collection, and that collaborating with "dataset owners" to leverage local knowledge is key to usability and enrichment of the data was voiced, but did not find much support.

Commercialization divides: An instrument for standardization, but misaligned with clinical culture

Commercialization is often viewed as a pathway to standardize and scale bioinformatics solutions, yet its role in clinical implementation remains contentious. In our survey, only 21.7% of respondents identified commercialization as the best, safest, and most efficient route from research to clinical practice. In contrast, 43.5% favored formal clinical–academic partnerships.

Participants voiced concerns that commercialization introduces conflicting values. In the Danish context, where healthcare is publicly funded and culturally positioned as a public good, many viewed profit-driven models as misaligned with patient care priorities (one stated "healthcare is not a business"). Several noted that commercialization risks shifting incentives from patient outcomes to financial gain, while also complicating trust and data sharing. The fragmentation of the Danish healthcare system and small market size (a population of ∼6 million, 30 public hospitals across five regions) further reduce incentives for industry to develop tailored solutions, increasing the cost and risk of adoption.

Several healthcare professionals gave examples of commercial products that eventually cost more to buy, than it would have cost to build locally, because adaptation to local infrastructure carries a large fraction of the total cost and draws on existing healthcare staff. Vendor lock-in was also seen as a risk.

Respondents highlighted a range of practical barriers to commercialization of locally developed solutions: lack of infrastructure, opaque regulatory requirements, absence of support for navigating intellectual property, and limited appetite among researchers to pursue entrepreneurial paths. There was a perception that commercialization often transfers public knowledge into private hands without clear public benefit, and an experience that tech-transfer offices both at university and hospitals frequently hinder rather than assist translation efforts. Both from research and clinic there was an articulated pressure and incitement structure from management toward public employees becoming entrepreneurs, which participants at the workshop did not fully understand the rationale behind.

Yet, during workshop discussions, there was consensus that commercialization can play a constructive role—especially in disseminating validated tools beyond their site of origin. Commercial channels may help enforce standards, reduce validation-time, maintain tools over time, and ensure broader uptake. To bridge the gap between public research and scalable deployment, participants emphasized the need for clearer support structures, improved tech-transfer functions, and mechanisms to ensure public return on publicly funded innovations.

Ultimately, while commercialization is currently not seen as a default route, it remains a useful instrument—particularly when securing the necessary economic foundation for scaling. Commercialization should also be integrated with efforts to simplify IT systems, adopt international standards, and maintain strong academic-clinical partnerships. Addressing skepticism toward commercialization will require equipping researchers and clinicians with the skills to recognize and leverage its potential benefits.

Reducing the time from ideation to implementation of clinical bioinformatics solutions

Despite steady innovation in bioinformatics, translating basic research to patient benefit remains slow and inconsistent. Participants cited a lack of institutional infrastructure, regulatory clarity, and coordination between stakeholders as key contributors to delays. When asked to identify the most effective pathway for moving solutions into clinical use, 43.5% of respondents favored formal, cross-institutional centers integrating academic and clinical bioinformaticians with practicing clinicians. Another 30.3% preferred bilateral partnerships between academic and clinical researchers. Many cited lack of public investments in clinical bioinformatics research as a barrier, and as many funding agencies view these projects as hospital production expenses rather than traditional research projects.

To accelerate implementation, the working group recommended a set of concrete measures: development of a centralized knowledge base, standardized regulatory templates, and universal validation processes. Improving institutional access to IT and regulatory expertise was also seen as essential. Respondents identified data governance, software engineering, and interdisciplinary project management as areas where workforce capacity is especially lacking. Participants called for harmonized test protocols, benchmarking tools, and expanded training for clinicians and developers alike. There is a need for dedicated funding for iterative clinical feedback loops in the development phase, which often require time from overworked frontline healthcare personnel. Additionally, anthropological studies of tool usage and clinician attitudes were proposed to guide the design of more user-centered solutions.

There was also recognition that for clinicians to adopt new tools, clear value must be demonstrated. Survey responses indicated that the most influential factors are demonstrated clinical benefit and ease of integration into existing workflows, followed by trust in robustness and availability of training and support. The identified barriers and proposed solutions are summarized in Table 1.

Discussion

Consensus

This consensus statement highlights key barriers and enablers for implementing bioinformatics tools in Danish clinical practice, based on input from experts across healthcare, academia, IT, and legal domains. While innovation in bioinformatics is rapid, its integration into clinical workflows remains slow, hindered by unclear regulatory pathways, fragmented data access, lack of standardization, and cultural resistance to commercialization.

Participants agreed that better coordination is essential, like others have previously identified the need for formalized cross-Institutional bridges that can assist early in framing research questions to deliver clinical impact, ensure ownership and adaptation [6]. Regulatory uncertainty must be addressed through accessible guidance, templates, and validation tools. Data access should be improved through centralized infrastructure, standardized metadata, and enforced deposition practices, as well as a National Metadata Registry. Scaling successful solutions across hospitals requires interoperable IT systems, stakeholder alignment, and long-term funding strategies. While commercialization remains controversial, it was acknowledged as a potential vehicle for dissemination, provided that tech-transfer systems are improved and public benefit is preserved.

Crucially, the survey identified widespread skill gaps in regulatory knowledge, data governance, and clinical-context awareness, highlighting the need for targeted training and interdisciplinary collaboration as also noted by others before us [7]. Respondents emphasized that clinical adoption hinges on demonstrated patient benefit and seamless integration into existing workflows, with trust, transparency, and usability being decisive factors.

Going forward, participants called for tangible pilot projects, especially around metadata registries, validation frameworks, and improved tech-transfer support, that can serve as examples. These efforts should be accompanied by systematic evaluation and workforce development to reduce friction from ideation to implementation.

Table 1 Problems and solutions in clinical bioinformatics implementation.

Identified barriers	Solution	Immediate steps
Lack of understanding of regulatory requirements	Develop centralized knowledge bases, regulatory templates, and training programs; embed compliance experts in translational research projects	Within each institution, designate a regulatory liaison and publish a two-page checklist summarizing MDR, validation, documentation, and data protection requirements for clinical bioinformatics projects.
Fragmented and inconsistent data access	Establish centralized data repositories with enforced deposition mandates, standardized metadata, and searchable inventories	Create and publish a national online inventory listing existing clinical datasets, their metadata summaries, and a named data steward contact for access requests.
Cultural resistance to commercialization	Improve tech-transfer processes, ensure public benefit from IP, integrate commercialization with academic–clinical strategies, train researchers, and clinicians to recognize the benefits	Encourage mid-stage translational projects to include a brief "implementation pathway" discussion with tech-transfer and clinical leadership to clarify scaling options, including non-commercial and commercial routes.
Limited institutional infrastructure for implementation	Build cross-institutional centers uniting academic and clinical bioinformatics with shared IT and regulatory support	Mid/low funding calls for Clinical-Academic research groups with large overhead for networking and training. Legal framework for sharing data, infrastructure and personnel between hospitals and universities.
Workforce gaps in compliance, data governance, and clinical context	Expand interdisciplinary training and support structures for bioinformatics developers and clinicians	Short mandatory introductory course on regulatory requirements, data governance, and clinical workflows for all new PhD students and clinical bioinformatics hires.
Unclear clinical objectives, criteria for success and scope for benchmarking	Develop harmonized test protocols and benchmarking tools. Establish success metrics and clinical use-cases	Dedicated team to aid translational bioinformatics projects to define clinical use-case, primary success metric, and predefined benchmarking dataset before development begins.
Disconnect between research and clinical practice	Create formalized collaboration models to align research goals with clinical needs early in development	Matchmaking events between research and clinic to foster shared funding proposals and projects. Consider academic researchers with clinical positions for dual affiliations at universities, just as is common practice for medical doctors.
Insufficient funding for implementation in translational research	Provide dedicated funding streams for iterative development and clinical feedback loops and software maintenance	Allocate a fixed percentage of existing translational research grants to protected implementation time for clinical validation and user feedback.
Complexity of integrating tools into existing clinical workflows	Design user-centered tools based on clinician workflows, supported by training and validation frameworks	Introduce mid-stage readiness review milestone evaluating clinical workflow fit, interoperability constraints, and existing technical debt.

With the right structures in place, bioinformatics innovations from academic research can more effectively deliver value to patients in the Danish healthcare system and beyond. We believe that the findings from this survey and workshop are relevant globally, and solutions applicable to any medical translational domain.

Feasibility

Several of the proposed measures could be implemented with relatively modest resources. Many of the immediate steps outlined in Table 1 primarily require coordination rather than large new infrastructures. For example, cross-institutional teams with expertise in regulatory, legal, and project management domains could help match clinicians and researchers early in translational projects and reduce uncertainty around implementation requirements.

Longer-term solutions will require coordinated action across funding bodies, universities, hospitals, and governmental institutions. Some initiatives already illustrate possible models for closer integration between research and clinical environments. In the Greater Copenhagen region, Clinical Academic Groups (CAGs) provide cross-institutional structures linking hospital clinicians and academic researchers. Similarly, the Technical University Hospital of Greater Copenhagen has begun offering academic affiliations to researchers primarily based in clinical settings, mirroring long-standing arrangements for medical doctors at university hospitals in many countries. While such initiatives do not resolve the broader implementation challenges identified here, they represent promising steps toward strengthening translational collaboration.

Data infrastructure developments also suggest that some of the recommended measures are realistic. Danish law requires central depositing of several health data types including genomic data, and across Europe, the European Health Data Space will require similar structures for every EU country before 2031. Additionally, Genome-phenome Archive, and SRA, and NCBI have fostered and supported such efforts for many years, though only by the force of free will, or journals requiring deposition.

Limitations

The number of survey respondents and workshop participants was smaller than desired. Participation was intentionally limited to enable us to invite all respondents physically for a workshop with in-depth discussion with contributions from all participants. These limitations and the availability of respondents may have biased the composition of respondents or restricted the breadth of perspectives captured. The analysis is grounded in the Danish healthcare system, whose

centralized structure, funding model, and regulatory environment may differ from those in other countries. Consequently, some barriers and proposed solutions may be specific to this setting. However, many of the challenges identified have also been reported internationally, suggesting that the broader principles and recommendations outlined here may generalize beyond Denmark.

Key Points

- **Regulatory uncertainty is a major bottleneck.** From all parts of the bioinformatics value chain there is a lack clarity on accreditation, validation, and legal requirements for clinical implementation, creating delays, and psychological barriers. The group recommends centralized guidance, regulatory templates, embedded compliance experts, and better training to integrate regulation early in development.
- **Fragmented data access severely limits progress.** Over 75% cited inconsistent availability, poor metadata, legal hurdles, and non-standardized formats as key obstacles. There was unanimous support for centralized national repositories with mandatory data deposition, standardized documentation, and active data stewardship to improve usability and scalability.
- **Commercialization is controversial.** While many see profit-driven models as misaligned with research goals and Denmark's public healthcare values, commercialization was acknowledged as a possible vehicle for scaling validated solutions. Improvements in tech-transfer structures, simple models for public return on IP, and stronger partnerships are needed.
- **Structural coordination and workforce gaps slow translation.** Implementation is hindered by weak institutional infrastructure, unclear success metrics, limited funding for implementation, and shortages in regulatory, data governance, and interdisciplinary skills. Proposed solutions include cross-institutional centers, harmonized validation protocols, dedicated funding for clinical feedback loops, and user-centered design aligned with clinician workflows.

Supplementary material

Supplementary material is available at *Briefings in Bioinformatics* online.

Conflict of interest

None declared.

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Data availability

Survey can be found in supplementary data.

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