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Helle Harder positions the Danish National Research Ethics Centre as a model for strategic regulatory innovation, aiming to boost Europe’s clinical trial competitiveness. By advancing AI integration, risk-based assessments, and cross-border harmonisation, Denmark is redefining ethical oversight. The Centre's leadership articulates a compelling vision where regulatory excellence becomes a catalyst for European life sciences advancement rather than merely a compliance hurdle.

Could you provide an overview of the National Research Ethics Centre’s structure and mandate within Denmark’s broader regulatory ecosystem?

Our organisation operates within a sophisticated dual-tier framework that encompasses both national and regional ethical oversight mechanisms. The national ethical system functions under ministerial authority, whilst we simultaneously oversee the regional research ethics infrastructure. Our national committee addresses appeals from the regional system and manages the most complex, emerging focus areas within clinical research ethics.

A distinctive aspect of our structure involves our national oversight of all trials falling under European Union legislation, in partnership with the Danish Medicines Agency. This represents a departure from the predominantly regional systems prevalent across Europe. Whilst most European

nations operate exclusively through regional committees, and only a limited number maintain national oversight capabilities, Denmark deliberately established this hybrid model from its inception.

The forthcoming Clinical Trials Regulation and Medical Device Regulation have prompted our transition to a purely national system for these domains. Additionally, we provide comprehensive guidance to the research community regarding ethical research standards and regulatory compliance frameworks.

Within the context of Denmark's Life Sciences Strategy, how does the Centre contribute to the nation's ambition to enhance clinical trial presence and competitiveness?

We position ourselves as an active strategic partner within the clinical trials ecosystem, both domestically and across the European Union. Our engagement with Denmark's Life Sciences Strategy extends beyond mere regulatory compliance. We actively contribute to strategic development and implementation of key performance indicators that drive measurable outcomes.

Our focus transcends simply making Denmark attractive for clinical trials, though that remains important. We advocate for a broader European perspective, encouraging other nations to adopt similar strategic approaches to elevate Europe's competitive position globally. Denmark's scale allows for rapid, decisive action, and we recognise our responsibility to serve as a catalyst for broader European advancement.

The Danish model can serve as an inspirational framework for other European nations, demonstrating how regulatory excellence can become a competitive advantage rather than an impediment to innovation.

The Centre recently completed a comprehensive analysis of the future ethics committee system. Could you elaborate on the methodology and key findings from this strategic review?

We conducted an extensive stakeholder engagement process, interviewing representatives across the entire clinical trials ecosystem. This encompassed sponsors from both industry and academic sectors, principal investigators, hospital systems, regional committees, committee members themselves, the medicines agency, our ministry, and crucially, patient representatives.

The analysis revealed four overarching strategic themes: scientific integrity, risk-based approaches, proportionate review processes, and challenges and considerations. The universal stakeholder request centred on implementing a risk-based assessment framework to replace our current standardised approach.

The existing one-size-fits-all methodology represents an inefficient allocation of resources, consuming valuable time on routine compliance reviews rather than focusing on substantive ethical considerations. The proposed risk-based approach would enable deeper engagement with complex ethical issues whilst streamlining standard applications.

Stakeholders emphasised that a proportionate approach would significantly enhance transparency and predictability for sponsors. Simple applications following established precedents would receive expedited processing, whilst novel, complex, or controversial protocols would undergo comprehensive review. This differentiated approach eliminates the current disconnect where experienced sponsors question extensive reviews for routine applications they have successfully completed multiple times previously.

We are currently implementing legislative frameworks that provide the authority to establish and operate risk-based assessment protocols, after which we will define the operational parameters and decision matrices.

How does this initiative address the broader challenge of consistency across European ethics committees?

Consistency represents the fundamental legitimacy of our system. Without predictable, uniform outcomes, our value proposition becomes questionable. We continuously strive to enhance consistency across all committees, recognising that this principle will likely generate significant discussion across Europe.

Many European systems exhibit such heterogeneity that they cannot meaningfully address consistency challenges. This creates scenarios where commercial sponsors receive diametrically opposed assessments for identical protocols across different countries. For example, one committee may rate a submission as exceptional whilst another considers it fundamentally flawed.

The absence of harmonised guidance for ethics committees, unlike the comprehensive framework available to medicines agencies, compounds this challenge. The integration of ethics committees into the European Union system represents a substantial undertaking, as we lack the institutional

knowledge and collaborative frameworks that medicines agencies have developed over decades.

Can you discuss the establishment and evolution of MedEthics EU, the European network you helped create?

Initially, we encountered significant difficulty identifying appropriate interlocutors for discussions about cross-border ethical system coordination. National ethical systems operated in complete isolation, with no knowledge of counterpart organisations or established communication channels.

This contrasts sharply with medicines agencies, which benefit from the European Medicines Agency's extensive infrastructure and decades of collaborative experience. Imagine removing that entire framework, erasing institutional knowledge of European Union procedures, and expecting aligned outcomes—that approximates the starting point for ethical systems.

Drawing on our background at the Danish Medicines Agency, we recognised the critical need for a collaborative forum. Working with counterparts in the Netherlands and Germany, we engaged the European Commission and stakeholders to establish this body. Once we identified the appropriate channels, enthusiasm was overwhelming.

Currently, representatives from twenty-six countries participate in monthly meetings. However, meetings alone prove insufficient without dedicated resources to execute work between sessions and develop tangible outputs. We are pursuing European Union funding to enhance national secretariat capacity, recognising that MedEthics EU's success requires both financial support and political endorsement from member states.

How do you balance national competitiveness with broader European collaboration objectives?

Our primary motivation centres on enhancing European Union competitiveness globally rather than pursuing narrow national advantages. Whilst competition between European countries may drive individual improvements and contribute to regional competitiveness, our fundamental objective involves creating an attractive European Union environment for clinical trials.

Denmark's strengths include strong governmental commitment to life sciences, an integrated ecosystem where stakeholders maintain close relationships, and a dialogue-oriented approach with industry. We operate an open forum where stakeholders can directly communicate challenges,

which we then address through our European Union collaborations.

Our focus on early-phase trials leverages our technical expertise whilst acknowledging our population limitations. Denmark possesses the scientific capabilities to contribute meaningfully to Phase I trials, establishing this as our strategic emphasis.

The Centre offers fourteen-day approval timelines for certain trials. How does this initiative function, and what strategic implications does it carry?

Under the previous directive, fourteen-day approvals were more straightforward to implement. The Clinical Trials Regulation introduces additional complexity and stricter timelines, making rapid approval significantly more challenging to achieve and therefore more valuable as a competitive differentiator.

Our focus on early-phase trials reflects sponsor priorities for abbreviated timelines during these critical development stages. This requires coordinated action with the Danish Medicines Agency to ensure parallel fast-track processing across both regulatory pathways.

These compressed timelines serve as a proxy for systematic efficiency. Dysfunctional systems cannot accommodate such demanding schedules, so our ability to deliver represents evidence of streamlined, effective operations. Sponsors recognise that rapid timelines indicate broader systemic capabilities beyond mere processing speed.

For multinational trials, we can guarantee fourteen-day processing whilst encouraging sponsors to identify other countries capable of matching this timeline. This approach utilises market forces to pressure other systems toward similar performance standards, ultimately benefiting European competitiveness rather than providing sustained Danish advantage.

How do you envision artificial intelligence transforming clinical trial ethics review processes?

Artificial intelligence will fundamentally redefine our case processing methodologies. We anticipate AI assuming responsibility for routine compliance verification, enabling our transition from a procedural control function to a strategic partnership role focused on scientific integrity, ethical complexity, and human-centred research considerations.

This transformation allows deeper engagement with substantive ethical issues and enhanced stakeholder guidance, replacing tedious administrative tasks that currently consume significant resources. We envision increased academic rigor and earlier collaborative engagement with sponsors to identify ethical challenges and develop solutions proactively.

AI cannot address ethical solution development or complex moral reasoning; these distinctly human capabilities will become our primary value contribution. The technology will enhance rather than replace human judgment in areas requiring ethical expertise.

Are you currently implementing AI technologies, and what lessons have you drawn from international experience?

We remain in exploratory phases, evaluating optimal integration approaches for our specific requirements. The FDA has approved AI-developed clinical trials, though we have not yet assessed the quality and applicability of their methodologies to our workflows. British colleagues appear more advanced in AI implementation, and we are establishing partnerships to learn from their experience.

Our institutional attitude toward AI remains positive and solution-oriented. Rather than debating theoretical advantages and disadvantages, we focus on creative applications that enhance our capabilities and allow resource reallocation toward higher-value activities. This approach should reduce research waste, improve data utilisation, and ultimately enhance patient safety through more focused ethical oversight.

How does the Centre address diversity and representation in clinical trials?

We consistently evaluate whether trial populations accurately represent the patient demographics likely to receive approved interventions. If inclusion criteria inappropriately exclude populations without scientific justification, such as excluding women from studies where gender is not relevant, we require protocol modifications before approval.

However, we cannot control which research topics sponsors pursue. While we might recognise knowledge gaps regarding specific populations, such as pregnant women with particular conditions, we can only ensure that submitted protocols meet quality standards and include appropriate populations for their research questions.

Our approach prioritises scientific relevance: if demographic characteristics matter for the target population, they must be reflected in the trial design. We do not mandate inclusion of ethnic or demographic strata unless scientifically justified for the research question.

What strategic priorities will guide the Centre over the coming years?

Three primary initiatives will drive our strategic direction: artificial intelligence integration into case processing, strengthening European Union research ethics harmonisation, and maintaining stakeholder dialogue to address emerging ethical challenges in rapidly evolving research environments.

The regulatory system must demonstrate comparable innovation to match the continuous stream of research innovation we encounter. We witness daily waves of technological advancement, requiring parallel regulatory innovation to maintain relevance and effectiveness.

Following the European Health Data Space development and increasing focus on health data utilisation, data ethics will become increasingly critical. We possess robust legislative frameworks and substantial data resources, particularly in Denmark, but we must ensure ethics does not become a bottleneck for health data applications. While we have not yet determined specific solutions, we maintain firm commitment to proactive engagement in this domain.

What message would you convey to your European colleagues regarding the future of clinical trial ethics?

We must evolve from being mere gatekeepers to becoming active partners in addressing the ethical challenges associated with emerging health technologies. This evolution requires both a shift in mindset and a significant allocation of resources, which the implementation of artificial intelligence can partly facilitate.

Crucially, the legislation needed for the successful harmonization of research ethics under the CTR is already in place. What remains is the political will to align efforts and allocate the necessary resources to the ethics system. This will enable it to match the role of the NCAs in the approval process, which began their harmonization across EU member states under the 2004 Directive. With the right commitment, we can achieve a similar level of professionalization across European the research ethics systems.

If we manage to achieve genuine harmonization across the European Union, we will position ourselves as the premier global region for clinical trial attraction, leveraging our high ethical standards as a competitive advantage. The potential impact is extraordinary: addressing the capacity bottleneck we sometimes represent could be resolved with a modest EUR 10 million annually across the continent. This small investment could accelerate or enable outcomes worth orders of magnitude greater in terms of pharmaceutical innovation value and health benefits.

However, funding alone will not suffice without political commitment. Resources must accompany a genuine dedication to finding collaborative solutions. We need this commitment replicated across all member states. With the right level of investment, we can unlock transformational outcomes for research ethics and clinical trials across Europe.

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