

Proceedings from the November 2024 Orange County Impact Conference

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Abstract

Background: Successful Research and MedTech collaborations depend on five key components: talent development, innovative solutions, regulatory compliance, patient-centered care, and rigorous validation. Institutional leaders frequently navigate multiple professional identities—simultaneously serving as educators, researchers, clinicians, and innovators—creating bridges between academic rigor and practical application that accelerate the translation of research into meaningful solutions.

The contemporary landscape presents significant challenges as institutions balance the pursuit of academic excellence with the need for rapid responsiveness to technological and commercial innovation. Traditional research processes, while ensuring quality, often impede the pace of advancement necessary in today's rapidly evolving environment. This tension necessitates structural reforms across multiple dimensions of institutional operation.

To cultivate a thriving research and innovation ecosystem, several essential components must be established:

First, institutions require agile research infrastructure with cutting-edge laboratories, specialized equipment, and certified research professionals specifically trained in device development and regulatory compliance. Online clinical management platforms can democratize trials and streamline data extraction for publication.

Second, a collaborative interdisciplinary network must foster cross-sector engagement through structured mechanisms like Innovation Exchange Forums and digital collaboration platforms that protect intellectual property while enabling continuous feedback loops among stakeholders.

Third, diverse talent pools must be recruited and retained through flexible employment frameworks that offer market compensation, varied teaching loads, and tailored research responsibilities. Non-traditional academic appointments require appropriate university status and promotion pathways to attract top talent from diverse backgrounds.

Fourth, funding diversification across government grants, venture capital investment, corporate partnerships, and philanthropic contributions creates sustainability for long-term research initiatives while encouraging commercialization pathways.

The evolution of these collaborative models holds transformative potential when properly designed and continuously evaluated. By reforming funding structures, shortening approval timelines, creating innovative incentive systems, and fostering deeper integration between academic researchers and industry partners, institutions can maintain commitments to excellence while becoming more responsive to market-driven demands.

Ultimately, these enhanced collaborative structures will enable the research community to navigate the complexities of modern development while fulfilling broader societal responsibilities through improved healthcare delivery innovation and community impact

Objective: The Orange County (OC) Impact Conference, held in November 2024, convened 180 key stakeholders from the life sciences, medical device, and healthcare sectors. CHOC Research in collaboration with University Lab Partners (ULP) and the

University of California, Irvine, provided this platform for leaders, decision-makers, and experts to discuss the intersection of innovation in research, healthcare, biotechnology, and data science.

Methods: We convened a multidisciplinary symposium (180 participants) to examine advancements in life sciences and medical device research development. The structured forum incorporated moderated panel discussions. Participants represented diverse stakeholder categories including research scientists, clinical innovators, investment entities, and executive leadership. The event design facilitated both structured knowledge exchange and strategic networking opportunities aimed at identifying implementation pathways to enhance clinical impact.

Results: The 2024 OC Impact Conference Proceedings outline a strategy for healthcare innovation, demonstrating how targeted collaboration between patients, families, researchers, engineers, data scientists, and industry is reshaping the healthcare innovation ecosystem. This integrated approach ensures every stakeholder's voice contributes to meaningful advancement, guiding resource allocation and partnership development across the life science and medical device sectors. Our findings demonstrate that success requires moving beyond traditional approaches to patient-driven research priorities, augmented design principles for medical device development, and direct engagement between innovators, research participants, industry and healthcare centers throughout the research development cycle.

Conclusions: The insights gained through participation in the OC Impact Conference contribute to the ongoing discourse in these fields, emphasizing collaborative efforts to enhance pediatric and adult healthcare outcomes. Clinical Trial: N/A

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Original Manuscript

Proceedings from the November 2024 Orange County Impact Conference

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15 Oracle, Los Angeles, CA

16 Remmie Health, Los Angeles, CA

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Abstract

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Results: The 2024 OC Impact Conference Proceedings outline a strategy for healthcare innovation, demonstrating how targeted collaboration between patients, families, researchers, engineers, data scientists, and industry is reshaping the healthcare innovation ecosystem. This integrated approach ensures every stakeholder's voice contributes to meaningful advancement, guiding resource allocation and partnership development across the life science and medical device sectors. Our findings demonstrate that success requires moving beyond traditional approaches to patient-driven research priorities, augmented design principles for medical device development, and direct engagement between innovators, research participants, industry and healthcare centers throughout the research development cycle.

Conclusion: The insights gained through participation in the OC Impact Conference contribute to the ongoing discourse in these fields, emphasizing collaborative efforts to enhance pediatric and

adult healthcare outcomes. By prioritizing collaboration and strategic communication, medtech and research innovators can expedite the evolution of ideas and solutions that enhance patient outcomes, optimize workflows, redefine workforce roles, and shift existing paradigms. This synergistic approach facilitates the rapid development of impactful innovations but also positions entities to significantly drive market adoption.

Index Terms—data science, healthcare, innovation, life sciences, medical devices, pediatrics

Clinical and Impact: The insights gained through participation in the OC Impact Conference contribute to the ongoing discourse in these fields, emphasizing collaborative efforts to enhance pediatric and adult healthcare outcomes.

INTRODUCTION

UNIVERSITIES and hospitals are multifaceted institutions that embody a diverse array of identities in research, community engagement, and broader societal development. These institutions are not monolithic; rather, they function as dynamic hubs that integrate academic research, clinical service, industry expertise, and community growth and impact. Within this context, universities and hospitals increasingly engage in public-private partnerships, government-sponsored initiatives, and outsourced service delivery models, all of which contribute to a rapidly evolving landscape.

By embracing a variety of operational frameworks, universities and hospitals can diversify their functions, adapt to shifting societal demands, and foster innovation. These partnerships and collaborations—spanning academia, industry, & government—facilitate the exchange of knowledge, and interdisciplinary research. Such models enable institutions to address pressing societal challenges while positioning themselves as leaders in the development and implementation of novel technologies, treatments, and new services.

There are 5 key components to a successful collaboration in MedTech: talent, approach and solution, regulatory compliance, patient care, and validation.

COMING TOGETHER TO GO BEYOND

University and hospital leaders frequently navigate multiple professional identities. Faculty, researchers, data scientists, and clinicians often balance roles as educators, mentors, service providers, and innovators. This integration of multiple identities is essential not only for advancing institutional missions but also for promoting the development of groundbreaking research that addresses the complex needs of patients and communities. Furthermore, such multiple roles help bridge the gap between academic rigor and practical application, thereby accelerating the translation of research into real-world solutions.

In particular, universities and research institutions face the challenge of balancing the demands of producing high quality academic research with the need to respond swiftly to the rapid pace of technological and commercial innovation. While the pursuit of academic excellence remains paramount, these institutions must also remain agile and adaptive to the fast-evolving landscape of industry and commercialization. To thrive in this complex environment, universities and hospitals must continually assess and refine their strategies, ensuring that they not only contribute to the advancement of knowledge but also play an active role in shaping the future of research and healthcare innovation. Only through these partnerships, and an evaluation and well-designed feedback loop of such partnerships, can the research community successfully navigate the complexities of modern research and development, while simultaneously fulfilling their broader societal responsibilities. The evolution and evaluation of these collaborative models holds the potential to transform how we approach research, healthcare delivery, and societal well-being.

A critical area for improvement lies in incentivizing and structurally supporting research and innovation. Traditional, rigorous research processes adhered to within academia, while valuable, can impede the rapid pace of technological and scientific advancement. There is a pressing need to evolve a more dynamic, responsive research ecosystem, by reforming funding structures, shortening

grant approval timelines, incentivizing quicker innovation, adding new roles, titles and personnel, augmenting the human resource systems, and promoting deeper integration of academic researchers and industry partners.

Such measures would enable academia to maintain its commitment to excellence in research while becoming more agile and responsive to the demands of a rapidly evolving, market-driven world. The authors also believe that academia needs to be more responsive and incentivized to apply their work in the community; this includes designing partnerships with industry, innovators and healthcare in the medtech space. This is critical to bringing that knowledge to bear on improving patient outcomes via new technology and devices.

To effectively advance research and innovation, several key components must be in place:

A. Agile and Responsive Research Infrastructure The availability of cutting-edge laboratories, specialized equipment, and opportunities for interdisciplinary collaboration and technologies is essential for conducting impactful research, particularly in areas that require advanced experimentation and data integration and analysis. Research professionals in support, technical or regulatory roles should be certified in device development and testing. In addition, an agile regulatory and trial environment locally, one specifically designed to facilitate device development is needed. Online clinical management platforms to engender democratized trials and automated reporting systems that can easily extract and publish trial data need to be developed and implemented.

B. Collaborative and Interdependent Ecosystem A collaborative and interdependent ecosystem will be fostering an environment that supports cross-disciplinary collaborations—spanning academia, industry, and government—to enable the exchange of knowledge, spark innovative thinking, and address complex challenges more effectively. We need a robust feedback loop that continuously integrates insights from academia, industry, and government stakeholders. This dynamic system must

facilitate real-time knowledge exchange, enabling rapid iteration of ideas and solutions while maintaining alignment with regulatory requirements and market needs. By designing structured pathways for cross-disciplinary collaboration, we can accelerate innovation cycles, reduce redundant efforts, and ensure solutions address real-world healthcare challenges effectively. Two critical strategies will drive successful implementation. First, establish quarterly Innovation Exchange Forums, like OC Impact Conference where academic researchers, industry developers, and regulatory experts engage in structured problem-solving sessions, focusing on specific healthcare challenges with defined metrics for success. Second, develop a Digital Collaboration Platform that enables continuous feedback collection, analysis, and implementation across the ecosystem, featuring standardized protocols for sharing insights while protecting intellectual property. These mechanisms ensure that innovations remain aligned with market needs while accelerating the path from concept to implementation.

C. Diverse and Skilled Talent Pool

Continuous and diverse investment in the recruitment, development, market compensation, and retention of highly qualified researchers, scientists, and engineers is essential for sustaining a robust research and development pipeline. This commitment ensures that institutions remain at the forefront of scientific and technological innovation. In order to continuously attract top talent, it is necessary to provide professional growth opportunities and to foster an environment conducive to long-term career development.

D. Flexible

Along these lines, one way to enhance institutional flexibility and support mentorship is through the diversification of faculty contracts. Faculty contracts that offer flexible work arrangements and titles that match their roles more comprehensively, and University status, benefit, or promotion for non-traditional academic appointments, market compensation, varied teaching loads, and tailored

research responsibilities allow institutions to attract and retain top talent with a wide range of personal and professional needs. By fostering a culture of mentorship within a flexible and supportive framework, institutions can enhance their capacity for knowledge transfer, skill development, and interdisciplinary collaboration, all of which contribute to the vitality and success of research and development efforts.

E. Diverse Funding Mechanisms

Access to a diverse array of funding sources is essential for the successful financing of long-term research initiatives. This encompasses government grants, which often provide substantial financial backing for innovative projects and serve to advance scientific knowledge and technological developments. Additionally, venture capital plays a pivotal role in promoting research endeavors that have significant commercial potential, offering not only financial resources but also strategic guidance and industry connections. Corporate partnerships are another vital component of funding for long-term research. These collaborations can foster innovation by bridging the gap between academic research and real-world applications, ensuring that discoveries can be translated into practical solutions that benefit society. Furthermore, philanthropic support from foundations and individual donors and family offices can provide critical funding that is often more flexible than traditional sources, allowing researchers to explore high-risk, high-reward projects that might otherwise struggle to secure capital.

Venture philanthropic and industry funding sources represent a paradigm shift in securing resources for innovative and clinical research, offering not only greater flexibility and immediate availability—eliminating the lengthy application cycles typical of traditional funding—but also a unique investment approach that prioritizes substantive returns. Unlike conventional foundation funding, which often aims to support researchers in securing subsequent grants, venture philanthropy is positioned to generate new revenue streams for foundations through returns on investment from

device development and commercialization. While not necessarily seeking exponential returns, these partnerships can strategically enhance foundation revenue, enabling expansion into new areas of support and furthering our mission in impactful ways. (Figure 1)

F. Data Infrastructure and Analytics

Improved access to data, incentivizing data analytics towards device development and - partnering with clinical collaborators -- are key to making sure that the solution supports the decision-making process, can be integrated easily into healthcare systems and clinical workflows.

The authors believe, evolution of AI in healthcare is advancing through two critical pathways: integrated device enhancement and clinical decision support. While AI is effectively optimizing medical devices that use sensors and imaging—often reducing costs while improving performance—the broader challenge lies in clinical implementation. Current algorithms, even within identical EHR systems, require significant local recalibration, creating inefficiencies across healthcare settings. Although successful AI applications exist in specialized areas like surgical planning and imaging analysis, the industry must pivot toward developing universal, generalizable algorithms. The solution lies not in better data management or analytics alone, but in creating adaptive algorithms that leverage Bayesian approaches to self-tune across various healthcare environments, implementing base algorithms with automatic local optimization capabilities.

AI can also be leveraged in combination with devices to improve predictions and lower costs of devices. However, locally derived AI can not easily be extended beyond a narrow tranche of patients, a medical specialty or specific institution. Next gen AI as a component of devices or as a standalone decision-tool requires data scientists to work in partnership with industry, especially EHR developers, inventors and healthcare providers to better leverage databases for AI-driven decision tools. To this end, more focus is required on developing algorithms that can be implemented across health care settings with built-in autotuning to local settings. Autotuning features will speed implementation and encourage broad application. of decision support algorithms. rather than locally

derived AI that cannot be extended beyond the specialty or institution.

G. Global Connectivity

Collaboration and dissemination on a global scale, facilitated by digital platforms and international partnerships, is vital for accelerating progress, sharing knowledge, and integrating diverse insights into the research process. A connected global research and patient subject infrastructure delivers significant advantages, notably through enhanced collaboration and knowledge sharing, which enable researchers, healthcare professionals, and institutions across various regions to synergize their expertise, data, and resources; this fosters expedited and comprehensive research outcomes that reflect the global context of diseases, facilitating the development of targeted treatments. Furthermore, this infrastructure promotes improved patient recruitment across diverse populations for clinical trials, opportunities for visiting scientists/researchers, thereby enhancing the representativeness of study results and enabling the collection of real-world evidence from a wide array of geographic and demographic settings—ultimately leading to a deeper understanding of patient responses and advancing the efficacy of personalized medicine, resulting in improved health outcomes worldwide.

H. Sustainability and Resilience

Ensuring that innovation practices are economically sustainable is key to aligning research outcomes with broader societal goals and ensuring long-term success. Furthermore, sustainable operations and practices foster a culture of collaboration and knowledge-sharing, allowing researchers and developers to share best practices and leverage collective expertise to create more impactful solutions.

I. METHODS

Siloed departments often hinder innovation in the healthcare sector. To address this, institutions, particularly university-affiliated hospitals, should create dedicated liaison teams that connect clinicians, engineers, technologists, industry leaders, FDA regulatory experts, and other stakeholders. These teams would identify existing solutions, evaluate the financial viability and resource availability for potential innovation, and determine whether the proposed innovation is likely to be feasible and effective. This approach would facilitate quicker decision making, reduce redundancy, and accelerate the bench-to-bedside timeline, ultimately improving patient care.

A notable discussion at the 2024 OC Impact Conference underscored the importance of solving real-world problems through product development, as opposed to simply creating innovative products for novelty's sake. Successful solutions must directly address a tangible problem and be applicable to end users. Volker Huther's point about the cost of **not** developing a product, as opposed to the cost of creation, highlighted the long-term consequences of inaction in medical innovation. Dr. Terence Sanger led a discussion of the evolving Medtech development pipeline, emphasizing that while the U.S. Food and Drug Administration (FDA) has streamlined its pathways and non-traditional funders are more involved, challenges remain in matching the right partners and identifying effective pathways early in the ideation and the development process. Developing a multi-lane pipeline tailored to the unique needs of MedTech is critical to overcoming barriers to FDA approval and ensuring that technologies are successfully brought to market.

The opening panel of the OC Impact conference, moderated by Dr. Sanger, focused on current challenges to the advancement and expansion of research innovation. Panelists highlighted the importance of clinician participation, protection of research time, and interdisciplinary approaches that incentivize collaboration. The elements identified as critical for success in healthcare innovation are funding, reimbursement models, and alignment of academic and industry timelines. Dr. Yama Akbari emphasized the importance of translating innovations into patient care, while Tom Andriola discussed the crucial role of reimbursement models in facilitating the implementation of new

technologies. The conversation further underscored the importance of industry-academic partnerships and the need for educational systems to foster cross-disciplinary collaborations that prepare students for future challenges in healthcare.

I. Keynote Summary: Dr. Kevin Ban's Insights on Healthcare Innovation

Dr. Kevin Ban, former Chief Medical Officer of Walgreens, delivered a keynote address that provided a comprehensive overview of the pressing challenges facing the healthcare industry and offered strategic direction for addressing these issues. Drawing from his clinical background and business acumen, Dr. Ban emphasized the importance of focusing on three core objectives when pursuing new healthcare innovations: improving diagnostic accuracy, enhancing operational efficiency, and reducing administrative burdens. He also advocated for the application of lean manufacturing principles, particularly the concept of "Going to Gemba"—the practice of directly engaging with the environments where work is performed. This approach, he argued, is essential for healthcare centers and startups in developing new products, so as to truly understand how their innovations will be used in practice, the barriers to adoption, and how the solutions will integrate into the daily workflows of healthcare professionals. Dr. Ban's message highlights the critical need for innovators to gain firsthand insight into the environments where their technologies will be deployed. A practical middle ground for implementing this philosophy lies in fostering more exploratory, open-ended conversations among the individuals experiencing problems firsthand—such as physicians, hospital staff, and patients—and those responsible for creating solutions, such as engineers, entrepreneurs, and tech developers. By establishing better communication channels, startups and innovators can engage directly with clinicians and healthcare administrators to better understand the problems they face and develop solutions that are both practical and effective. An example from his experience underscores the importance of this direct engagement. "During a recent visit to an

intensive care unit, I observed an infusion pump trigger an occlusion alarm, yet no notification was sent to the nurse's station. The problem was only addressed because another nurse happened to pass by. This simple issue—an inadequate notification system— was within my team's capability to resolve, but without the direct, in-person observation, I would never have known this gap in the system existed. This example illustrates the value of real-world, in-context engagement with healthcare professionals, enabling the development of tools that truly meet the needs of users."

Dr. Ban delivered a powerful message on the importance of understanding the nuances of the healthcare ecosystem, particularly within the neonatal and pediatric spaces. He highlighted that a deeper understanding of these specific healthcare environments and workflows is essential for innovators looking to design solutions that align with the realities of patient care. He also touched upon the unique challenges that clinicians face when transitioning into entrepreneurship, particularly acquisition of the business skills necessary to navigate the commercial landscape. A more robust framework for acquiring and accessing these business competencies would be invaluable for clinicians seeking to bring their innovations to market. The key takeaway from his keynote was the importance of leveraging multidisciplinary teams to foster collaboration across fields, to link medical professionals to engineers and business leaders. By combining expertise from diverse domains, healthcare innovators can more effectively address the complex challenges that permeate the industry.

In a subsequent discussion, Dr. Ban addressed the inherent complexities of healthcare innovation, particularly the regulatory challenges that differentiate healthcare from other industries. Moderator Dr. Sanger raised a pertinent question about how innovation in healthcare could transition from a traditional product development model to a more comprehensive approach that considers the entire healthcare delivery system. Dr. Ban acknowledged that healthcare is highly regulated, which can pose significant challenges to the adoption of new innovations in healthcare, which comprises a substantial portion of the global gross domestic product (GDP). He further emphasized the

importance of reverse-engineering solutions to meet the specific needs of healthcare systems, rather than merely developing solutions and expecting health systems to adopt them. Dr. Ban pointed out the necessity of developing solutions that integrate seamlessly into existing healthcare workflows and align with the practical realities faced by providers, and of understanding the intersection between lifestyle factors and medical care, particularly in managing chronic conditions such as diabetes and hypertension.

Dr. Ban's focus on the importance of solutions that not only address clinical problems but also facilitate integration into the workflow of healthcare professionals reinforced the need for user-centered design in health technology. Constraints faced by healthcare systems include tight margins and limited funding for experimental innovations, necessitating innovations that directly improve care delivery and patient outcomes. Furthermore, understanding the perspectives of both patients and payors—particularly with regard to reimbursement models—is crucial for the successful adoption of new technologies.

The keynote panel concluded with a reflection on the potential of artificial intelligence (AI) to transform healthcare, particularly in improving efficiency and addressing provider shortages. Dr. Ban cited examples such as Walgreens' efforts to leverage AI in streamlining administrative tasks, improving diagnostic accuracy, and increasing operational efficiency. He noted that while AI has the potential to drive significant improvements in healthcare delivery, it must be carefully aligned with the needs of both providers and patients in order to achieve meaningful impact. Dr. Ban's keynote highlighted the importance of a holistic, interdisciplinary approach to healthcare innovation.

By emphasizing the need for real-world engagement, cross-disciplinary collaboration, and a deeper understanding of healthcare systems, Dr. Ban outlined a clear path forward for the next generation of innovators seeking to improve healthcare delivery and outcomes. The future of healthcare innovation lies not only in technological advances but also in fostering better

communication, understanding, and collaboration across all stakeholders in the healthcare ecosystem.

J. Cultivating a Thriving Translational Research Ecosystem

The landscape of healthcare innovation and data science is experiencing a paradigm shift, characterized by the explosion of data availability, advanced computing power, and an increasing number of software engineers and coders who are driving the development of models and algorithms. While this influx of technological capabilities has opened new possibilities, it has also introduced what can be described as "p-hacking"—a reliance on statistically significant results that are often devoid of strong clinical foundations. This approach, while yielding insights, may lead to misguided conclusions. This will also happen when the emphasis is misplaced on quantity over quality, and algorithms over insights, with the assumption that more data, more techniques, and more programmers automatically lead to better outcomes.

A significant concern in the current data-driven healthcare landscape is that many models are generated through the use of pre-programmed libraries, often by programmers with limited domain-specific knowledge. This disconnect can be especially problematic in fields like medical research, where the integration of subject-matter expertise is critical for ensuring that models are not only statistically sound but also clinically relevant. For example, in medical research, it is insufficient to rely solely on software engineers, biostatisticians, and data scientists to drive advancements in complex domains such as cancer research. While their technical skills are invaluable, these professionals must not only collaborate more closely with domain experts, such as physicians and clinicians, to ensure that the methods they employ are valid and appropriately aligned with the realities of patient care but also refocus their technical skills in support of device development. Historically, researchers have worked alongside biostatisticians who were trained in the

fundamentals of statistical analysis, which provided the necessary rigor to ensure that research findings were both valid and reliable. However, with the increasing involvement of software engineers and citizen data scientists in healthcare, there is growing concern that many models are being developed without the statistical and clinical expertise necessary to appropriately estimate and interpret them accurately. The statisticians who attended OC impact discussed the fact studies estimate that up to 50% of published medical research may be underpowered, a clear indication of the

While the increasing prevalence of data science professionals with little to no formal statistical training may exacerbates one problem, namely internal validity and highlights the urgent need for more extensive training in the foundations of statistics and research methodology within the data science community, more statistical training is not all that is needed. As healthcare increasingly relies on AI and machine learning, it is essential that these technologies be designed and implemented by professionals who not only understand the technical aspects of these tools but leverage their knowledge to improve generalizability. Data-driven models that exploit large data sets operate under the assumption that more data equals generalizability. AI algorithms should be tested beyond a single data set, no matter how large. The inherent biases in data sets can only be managed with multiple input sources, Data science should utilize simulation and other methods to develop a deeper understanding of the theoretical underpinnings and assumptions they are modeling. While simulations can be a valuable tool, the heavy reliance on prior probabilities, assumptions and approximations necessitates a critical approach. Simulations can also be used more effectively to inform device development. Virtual patients created from informed empirical data can be readily utilized when data scientists collaborate with medical providers and inventors. Collaboration with medical providers and inventors is critical in creating optimized AI. A focus on data without adequate collaboration —often summarized as "garbage in, garbage out"—poses a serious risk to the validity of conclusions drawn from machine learning models as components of devices or as stand-alone

decision tools.

The rise of synthetic trials and simulated data provides great opportunity but may also complicate how data-driven models are utilized in device development. Data generated in eclectic or decentralized ways may not accurately reflect real-world complexities. The future of healthcare innovation requires a balance between cutting edge computational methods and a solid grounding in clinical reality. Thus, there is a compelling need for a more interdisciplinary approach to healthcare research and innovation—one that integrates the technical expertise of software engineers, data scientists, and biostatisticians with the clinical and medical knowledge of physicians and researchers. As much as the field benefits from advances in AI and machine learning, it is equally important to invest in the philosophical foundations of science, particularly in areas such as validity, reliability, and model interpretation. Further, Cloud laboratories are scaling. A cloud lab is an advanced, fully automated facility controlled entirely by software, enabling researchers to design, execute, and analyze experiments remotely from any location worldwide. This innovation signifies a remarkable technological advancement, providing extensive oversight over all wet lab processes, including sample preparation, experimental execution, method optimization, and scalability. Cloud labs transform the conventional paradigms of scientific research, expanding access and enhancing efficiency. Embracing these novel labs can also serve as an engine for device development.

K. Research, Development and Partnership of Medical Technology

The integration of patients into the early stages of medical technology development is crucial for ensuring that innovations meet real-world needs and are effectively aligned with healthcare delivery systems. A key framework for achieving this integration is the National Institutes of Health

(NIH)/National Science Foundation Small Business Innovation Research (SBIR) program, which encourages investigators to think holistically from the outset of product development. This includes considering not only the technical aspects of innovation—such as creation of the first 3D-printed prototype or the initial lines of code—but also the broader issues related to commercialization, reimbursement, and market adoption. By requiring innovators to address these concerns early on, the SBIR framework helps mitigate the risk of developing products that may be technologically feasible but ultimately fail to meet the economic or practical requirements of the healthcare system.

The FDA Pediatric Device Consortium (PDC) Program serves as a model of a successful network supporting MedTech innovators through each stage of research and commercialization. The PDC Program's comprehensive approach equips companies with the necessary resources and guidance to navigate the complexities of healthcare innovation, from early-stage research through to market introduction. Such networks are instrumental in bridging the gap between scientific discovery and practical application, ensuring that innovations are not only scientifically sound but also commercially viable and aligned with the needs of patients and healthcare providers. There is a need for more programs like this that can provide the structure, resources, and expertise to foster collaboration among research institutions, industry stakeholders, and healthcare providers. These organizations can help ensure that medical technologies move from the research phase to real-world clinical application in a way that is efficient, effective, and financially sustainable. While the increasing volume of data and the power of machine learning provide tremendous opportunities, these advances must be accompanied by a strong foundation in scientific theory, statistics, and domain specific knowledge. By fostering more interdisciplinary collaboration among researchers, data scientists, engineers, and clinicians, we can ensure that healthcare innovations are not only technically advanced but also clinically relevant and methodologically sound.

L. Generative AI in Research and Healthcare

The ongoing discourse surrounding the application of generative AI (Gen AI) in healthcare has the potential to transform both patient care and the professional lives of healthcare providers. AI's utility in healthcare is truly realized when it alleviates burdens rather than adding to them. Advancements in natural language processing (NLP) have enabled the development of clinical tools that can effectively automate tasks such as scribing medical notes. By reducing the administrative load on healthcare providers, these solutions allow physicians to spend more time engaging directly with patients, thereby enhancing the quality of care.

Through its ability to analyze large-scale datasets, AI may be able to address longstanding inefficiencies within healthcare workflows. One case in point was the use of AI at Providence Hospitals to address the persistent issue of outdated and inefficient technology, such as fax machines, in healthcare settings. Rather, AI should serve to streamline operations, allowing healthcare teams to focus on more complex and impactful tasks.

Nonetheless, amid the excitement surrounding AI, it is crucial to maintain a discerning perspective on its application in healthcare. As AI technologies, including machine learning and generative models, become more pervasive, we must acknowledge that some healthcare challenges may not require an AI-driven solution. The integration of AI into healthcare systems must be done thoughtfully, with due consideration of potential implications, including the risk of exacerbating physician burnout and ethical concerns related to workforce displacement. In particular, there is a real risk that healthcare administrations may leverage AI advancements as a justification for downsizing staff, inadvertently increasing clinician workloads and perpetuating the very issues that AI is intended to resolve.

Moreover, while AI can deliver substantial improvements in healthcare efficiency, the field is not without its challenges. A high bar must be used for critical assessment of Gen AI tools, particularly

with regard to their clinical applications. Although Gen AI systems such as GPT-4 have demonstrated substantial improvements in performance, significant concerns remain, such as the risk of adversarial attacks and the operational challenges of scaling AI tools for real-world clinical use. The deployment of AI in healthcare requires the establishment of stringent guardrails to ensure that these tools are used safely and effectively, particularly in high-stakes clinical environments.

The ethical implications of AI in healthcare must be considered carefully. While AI can enhance clinical decision-making, it cannot—and should not—replace human expertise. The relationship between healthcare providers and AI should be viewed through the lens of collaboration, where AI is seen as a tool to augment the clinician's capabilities, rather than as something that will supplant the clinician completely. One panel recommendation was to focus on understanding how clinicians make decisions and designing AI solutions that support this decision-making process. AI's role in healthcare is not primarily to make diagnoses; rather, it should be about enhancing the clinical reasoning process by providing evidence-based insights and reducing cognitive load. Panelists also highlighted the critical importance of ensuring transparency and accountability in AI systems. For example, understanding how AI models generate their outputs—whether they be in the form of diagnoses, treatment recommendations, or operational suggestions—is vital to establishing trust in these systems. Without clear mechanisms for detecting and mitigating errors such as "hallucinations" (unintended AI-generated misinformation), the deployment of AI tools could lead to harmful consequences, particularly in healthcare settings where decisions can directly impact patient outcomes—sometimes, irreversibly so. The distinction between "misinformation" (intentional falsehoods) and "hallucination" (unintended errors) was emphasized, with the panel acknowledging that we are not yet at a stage where AI can reliably replace human judgment, especially in complex clinical contexts.

One of the most significant barriers to AI adoption in healthcare is the challenge of seamless workflow integration. As Lindsay Mico from Providence Health noted, automating administrative

tasks such as fax processing or referral management can significantly improve efficiency, if these changes fit into existing work structures without disrupting care delivery. Moreover, artificial intelligence (AI) presents a significant opportunity for enhancing the skillsets of caregivers across diverse contexts. For instance, Providence Health is pioneering the development of an innovative conversation coaching tool designed to facilitate clinicians' proficiency in navigating challenging palliative care discussions. In this model, AI effectively assumes the roles of both patient and coach, providing clinicians with a unique platform to refine their communication skills and improve patient interactions.

A 2025 paper published in *The Lancet Digital Health* indicates that AI can significantly enhance cancer detection in mammography screening while reducing screen-reading workloads. Key findings from the MASAI trial reveal a 29% increase in cancer detection with AI-supported screening versus standard double reading, without negatively impacting recall rates, false positives, or consensus meetings. Moreover, AI primarily improved the detection of small, lymph-node negative invasive cancers, as well as specific aggressive cancer subtypes, while maintaining safety against overdiagnosis of low-grade lesions. Despite these promising results, further prospective trials are necessary to evaluate the clinical impact, interval cancer rates, and cost-effectiveness of AI in mammography screening.ⁱ

John Henderson of CHOC emphasized that careful consideration must be given to the development and implementation of AI tools that ensure safety, quality, and ethical standards. AI solutions must be continually benchmarked and evaluated to ensure that they do not produce misleading or harmful outputs, particularly as healthcare providers begin to rely on them more extensively. We must ensure that AI technologies are developed, deployed, and monitored with the highest standards of ethical practice, software development and cybersecurity best practices, and clinical efficacy. By focusing

on collaboration between AI systems and healthcare providers and designing these systems to fit seamlessly into existing workflows, we can maximize the benefits of AI while minimizing its risks.

M. Reimagining Funding and Investing Mechanisms for MedTech and Biotech

The panel on funding and investing in MedTech provided valuable insights on the current landscape but did not include a perspective from the "other side of the table," such as a company that is currently receiving investment or has recently undergone acquisition. Early-stage MedTech startup founders described bootstrapping to secure initial funding through business competitions, accelerator programs, government grants, and angel investors. Securing investment is often contingent upon strong early data and, to some extent, luck. The fortunate startup will connect with investors who are genuinely passionate about the mission or specific sector in which the startup operates.

The future of MedTech and biotech funding must go beyond traditional models that rely heavily on private investment and venture capital. Pursuing government grants, such as those from the NIH, presents a significant challenge. These grants, while non-dilutive and attractive for early-stage companies, involve lengthy review processes, often six to nine months. Moreover, the success rate for SBIR submissions is relatively low—around 16%, with even lower success rates for first-time applicants (NIH Data Book, 2023). As a result, while these grants are highly appealing, the odds of success for early-stage teams are slim. Early-stage proposals that incorporate supporting preclinical data are more likely to secure funding but are harder to achieve for bootstrapped early-stage MedTech start-ups.

Acquisition of the startup is another way to secure funding. However, this process can be arduous and protracted, even for companies with established revenue streams. Potential acquirers often face constraints related to market size, focus areas, or whether the company targets underserved populations, such as pediatric care. Pediatric focused MedTech companies encounter unique

challenges in securing capital. Following the pandemic-driven investment surge, the MedTech and biotech sectors are experiencing a cooling-off period.

By focusing on close collaboration between the funding and investment community AI systems and healthcare providers by engaging clinicians, data scientists, IT specialists, and administrators at every stage of development, and designing these systems to fit seamlessly into existing workflows, we can maximize the benefits of AI while minimizing its risks. This involves co-creating AI solutions that align with real-world needs, ensuring they integrate smoothly with existing electronic health record (EHR) systems and care pathways, and establishing robust feedback loops for continual monitoring and improvement. By keeping a human-in-the-loop oversight, we reduce the chance of errors or bias, prevent disruptions to patient care, create solutions that are desirable and will be used in clinical practice, and ultimately improve clinical efficiency and outcomes.

Cross-sector support could be pivotal. For instance, disease-specific associations, such as the American Heart Association, could enhance their commitment to investing in companies targeting conditions that are related or co-morbid with heart disease, such as diabetes. Additionally, there is a need for more programs dedicated to facilitating clinical trials and funding opportunities for pediatric-focused companies, which could help mitigate the perceived investment risk in this underserved sector and encourage more ventures to develop solutions for pediatric populations.

Panelists highlighted the value of meeting with a diverse group of investors, with varying perspectives and access points. The opportunity for post-event engagement with investors at the OC Impact conference proved valuable, though further information on family offices, which represent a viable funding option for early-stage companies, was not provided. Accessing investors remains a challenge due to the opaque nature of this funding source.

A separate session focused on providing actionable advice for Healthtech and medtech startups in pitching to venture capitalists (VCs). The session emphasized several critical elements for

successfully navigating the process of securing investment: building partnerships, understanding the application process, and preparing for the rigorous vetting procedures that often accompany funding opportunities. Panelists underscored the importance of having an immaculate pitch deck tailored to the specific investor being pitched. Beyond the technical aspects of the pitch, it is essential to demonstrate a clear understanding of the unmet medical need, the path to market, and the timeline for achieving clinical and commercial milestones.

Those seeking funding are advised to identify internal champions within VC firms who can assist with navigation of the investment process, identify potential gaps in the proposal, and lend credibility to the business concept. These relationships must be cultivated throughout the lifecycle of the startup. Finally, the successful founder will understand the importance of achieving product-market fit and be able to pitch key stakeholders in the healthcare ecosystem, including payors and providers.

Startups are advised to have a focused and well-defined strategy for successful exit. Several success stories were shared, including those related to personalization apps and devices addressing cardiovascular diseases such as atrial fibrillation and stroke, with emphasis placed on the importance of reimbursement and the role of funders in facilitating large-scale clinical trials. While private funding has been a key driver of innovation, it is essential to recognize that MedTech development often does not reflect the broader health needs of the population. Many devices are developed with a focus on market potential rather than critical public health issues. There is a growing need for greater public sector involvement in MedTech development to ensure that the technologies being funded align with the health priorities of underserved and marginalized populations.

The public sector, with its capacity for long-term, sustained investment, can play a pivotal role in balancing the interests of private investors and public health needs. This is particularly important in ensuring that MedTech and biotech innovations are not driven solely by profit motives but are also directed towards solving real-world health problems. Public funding takes various forms, from state investments and public bonds to local community tax initiatives. These approaches would not only

democratize MedTech funding but also ensure that investments are directed toward areas with the greatest need.

One challenge with public funding is that universities, while central to MedTech innovation, often have conflicting goals. Universities tend to prioritize the protection of intellectual property and the interests of their founders, which can sometimes hinder the push for more progressive funding mechanisms. However, alignment between university funding strategies and public health goals could shift the landscape of innovation towards more equitable outcomes. Public bonds, for example, could allow communities to directly invest in MedTech, so that innovation is not solely driven by the interests of venture capital or large corporations but, rather, by the needs of the public.

N. Possibilities for Evidence Generation to Accelerate Regulatory and Research and Development Pathways

Representatives from the FDA and academic institutions, together with startup founders and regulatory consultants, discussed strategies to expedite the approval process for medical devices. Key insights included the necessity of maintaining frequent communication with the FDA, understanding the existing and new requirements of the regulatory process, and identifying appropriate contacts within the FDA. Panelists highlighted ongoing efforts to enhance transparency and encourage proactive engagement from the FDA such as via FDA presubmissions (pre-sub), especially with the development of pediatric MedTech. FDA representatives emphasized that the review process is conducted by experts who provide thorough, evidence-based evaluations that may uncover fundamental flaws or areas requiring further refinement. The panel underscored the importance of building strong, collaborative relationships with the FDA and seeking pre-screening consultations to ensure that a proposal is well structured and comprehensive. A company's mission must be aligned with the FDA's goal of safeguarding patient health while fostering technological innovation.

Panelists suggested that statisticians and other subject matter experts be recruited to strengthen the proposal's scientific rigor. To develop a market-viable medical device, startups should connect with payors to understand coverage aspects and solicit advice from physicians on adoption strategies. To assist with proposal submission, the FDA can facilitate discussions between commercial entities and payors and offers a wealth of resources and guidance on its website. When asked whether the FDA has ever advised against advancing a proposal, the panel noted that they carefully evaluate whether the benefits of a proposed device outweigh the risks. In cases where the risks are deemed too high, the FDA may recommend modifying the proposal before resubmission or, in rare cases, advise against pursuing it altogether. Despite the growing opportunities for utilizing diverse forms of evidence to support new technologies, startup members must be able to defend the use of alternative evidence based on expertise in experimental design, data analysis, and methodological rigor. Universities must redesign educational programs and fellowships to equip graduate students with essential technical skills and hands-on experience during their academic training. For example, advanced degree programs that include courses on alternative evidence, alongside internships tailored to these needs, would better prepare the next generation of regulatory professionals.

Collaboration with technology partners will be essential for advancing alternative evidence strategies in the development of new hardware and software solutions. The creation of certification programs in alternative evidence could help cultivate the expertise required to navigate this evolving regulatory landscape. Finally, there is a pressing need for more robust incentives within academia to accelerate research and innovation. Academia tends to follow a rigorous, high-quality process, while startups often prioritize speed. Bridging this gap requires a more integrated approach that combines the thoroughness of academic research with the agility of startup-driven innovation. Universities should consider rethinking traditional research cycles, such as the typical five-year grant timelines, and explore new models that incentivize researchers to shorten development timelines, thereby aligning more closely with the needs of industry.

III. REGULATORY AND ETHICAL CONSIDERATIONS IN PEDIATRICS

Conducting clinical trials for pediatric medical devices presents a range of unique challenges, primarily due to the small, heterogeneous patient populations involved, which are often spread out across multiple institutions. This dispersion of participants can complicate the generalizability and consistency of study findings. Maintaining blinding in pediatric trials is particularly difficult, as is ensuring that the use of study blinding or sham devices aligns with ethical standards for critically ill children. Furthermore, local Institutional Review Boards (IRBs) may lack specialized expertise in pediatric medical devices, leading to delays in study approval. Dr. Frances J. Richmond, Professor Emerita of Regulatory and Quality Sciences, described challenges related to pivotal trials for Class III devices—those designed to provide primary clinical data to demonstrate "reasonable assurance of safety and effectiveness"—when conducted in pediatric populations. Similarly, for Class II devices that require regulatory clearance, identifying an appropriate predicate device can be challenging, especially if no similar devices have been approved for pediatric use. After regulatory approval has been secured, postmarket surveillance in pediatric populations presents additional complications due to the unique risks and needs of younger patients.

The regulatory landscape for medical devices has become increasingly complex over the past several decades, resulting in significant uncertainty and prolonged clearance times that place substantial financial pressures on developers, particularly small companies focusing on pediatric devices. Moreover, ethical considerations surrounding consent and assent, as well as the comfort and acceptance of parents, are paramount in research involving critically ill children. The absence of enforceable standards for medical device age labeling further complicates device selection and usage across different pediatric age groups. Variability in the expertise of FDA reviewers in pediatric device regulation adds another layer of complexity to the approval process and safety assessment.

Several promising initiatives have made progress in addressing these issues. Narrowing the gap in

pediatric device development will require broad cooperation among stakeholders across industry, academia, patient advocacy groups, healthcare providers, investors, payors, regulators, and Congress. Given the heavily regulated nature of the medical device market, legislative and regulatory mechanisms that incentivize and require change will be essential—but only with the appropriate prioritization and funding from Congress and the FDA (American Academy of Pediatrics 2022).

IV. HEALTH CARE AT HOME AND BEYOND THE HOSPITAL

The transition of care from hospital to home is an increasingly critical topic, particularly as advancements in data science, AI and machine learning continue to shape medical technology.

In 2000, clinicians described the hospital-at-home as a service that provides active treatment by healthcare professionals, in the patient's home, of a condition that otherwise would require acute hospital in-patient care, always for a limited period. Now, in 2024, the Hospital-at-home has become a popular response to the increasing demand for acute hospital beds, and as the demand for in-patient care continues to rise, Hospital-at-Home has emerged as a strategic solution to optimize resource allocation and enhance patient outcomes.

Home Health services often prioritize preventive care, wound management, and rehabilitation for patients in their residences, focusing on maintenance care, disease management, and therapeutic rehabilitation. These services typically entail intermittent visits from healthcare professionals, including physical and occupational therapists, patient educators, and registered nurses, aimed at helping patients sustain functional abilities, manage chronic conditions, and recover from injuries or illnesses. Ideal candidates for Home Health include individuals requiring post-discharge care after hospitalization, rehabilitation services, and management of chronic conditions such as arthritis or congestive heart failure.

The panelists, which included research executives at Hoag and clinicians highlighted the

importance of aligning AI and ML tools with the decision-making processes of clinicians and healthcare providers, which comprise more than just a diagnosis, but make patient care and decision-support easier. The panel thoroughly explored the transition from hospital-based care to home healthcare, focusing on the opportunities this shift presents for commercial entities. Notably, the inclusion of a parent advocate or expert could have provided a more well-rounded perspective.

A key distinction was made between home healthcare, where healthcare professionals visit patients in their homes, and "hospital-at-home" models, in which patients are able to access high-end medical technologies within the home, mimicking the hospital environment. The panel emphasized that aligning all stakeholders from the outset—particularly in terms of reimbursement structures—is crucial for the success of such initiatives. Demonstrating improved patient outcomes, especially for conditions like hip replacement, was identified as vital for securing continued support for the hospital-at-home model.

AI tools were discussed as playing a pivotal role in home care, primarily for monitoring and assisting in prevention. While brick-and-mortar hospitals continue to face rising costs, some of which threaten their viability, there are clear benefits to implementing hospital-at-home models. However, the panel cautioned that resistance from hospital staff—due to a lack of trust in the hospital-at-home model—may pose a challenge. Ultimately, the success of these models will depend on patient preferences and the financial sustainability of hospitals. While the panel discussion was insightful, the inclusion of a parent advocate or expert could have provided a more well-rounded perspective, especially concerning the challenges and needs associated with the transition from hospital to home care, with the hospital-at-home providing a potential solution to mitigate costs.

Panelists expressed optimism about the role of hospital-at home in the future, with a particular focus on three key outcomes: (1) reducing readmissions through the use of AI robots to assist patients; (2) mitigating delirium; and (3) reducing inpatient stays by 20%. These goals highlight the potential for home-based care to reduce the burden on traditional healthcare settings, improve patient

outcomes, and lower overall healthcare costs. There are, however, concerns about how clinicians perceive the shift toward home-based care. With at-home products touting 24/7 access to clinicians and 24/7 real-time data streaming dashboards that require physicians to sift through, these products can exacerbate physician burnout, a problem it was trying to solve. Many clinicians are also critical of at-home care solutions because they feel threatened by the notion of being replaced by technology, which may limit their willingness to support clinical trials conducted in home settings or with home-based patient rosters. Likely proponents of care-at-home initiatives would be street medicine and mobile health providers, as well as public health professionals. Pharmacy benefit managers and health maintenance organizations (HMOs) are potential stakeholders with vested interests in reducing healthcare costs, which makes them valuable partners for MedTech startups. Early engagement with large industry players, such as Walgreens or Kaiser Permanente, could help MedTech companies refine their models and secure essential funding, although concerns about how such partnerships might impact company valuations must be addressed.

A particularly interesting observation was made regarding the role of real estate prices in influencing individuals' preferences for where they would like to die, with many expressing a desire to stay at home despite the inherent risks associated with home care. Homes where deaths occur, particularly in sensitive or high-profile circumstances, may experience a decline in perceived market value. Buyers often associate such properties with negative connotations, which can dampen demand.

Accelerating the development and deployment of home-based monitoring devices, particularly for routine interventions, holds great potential for alleviating pressure on hospital systems and freeing up valuable bed space. In terms of opportunities for innovation, the panel highlighted three key areas where "bringing the hospital home" could have the greatest impact: (1) pre-emptive emergency room screening; (2) remote monitoring of high risk, chronic patients or those at risk of recurrence; and (3) post-discharge care and monitoring. Devices such as e smart otoscopes

with integrated telemedicine capabilities that can enable real-time video streaming and remote monitoring through a purpose-built app, allowing healthcare providers to conduct virtual examinations and track patient conditions could significantly enhance care in these three domains, providing a bridge between home-based care and traditional hospital settings while improving patient outcomes and reducing healthcare system burden. This shift towards home care and hospital-at-home models represents a critical evolution in healthcare delivery, one that holds promise for both improving patient care and addressing systemic challenges faced by traditional healthcare infrastructure. As technology continues to advance, particularly in the realms of AI and machine learning, the potential to optimize these models and expand their reach will be pivotal in reshaping the future of healthcare.

V. ENGAGING PATIENTS AND RESEARCH PARTICIPANTS: ENHANCING EXPERIENCE AND JOURNEY

The patient experience in healthcare is frequently compromised by several key shortcomings, including brief and rushed clinic interactions, inadequate outpatient monitoring infrastructure, high cost, and insufficient support for patient health literacy. These challenges contribute to the reinforcement of existing health disparities. For instance, when a patient and provider do not share a common language, time is lost in arranging for an interpreter, ultimately reducing the time available for meaningful communication and care. Moreover, low health literacy can result in misunderstandings about the rationale behind clinical decisions, which can adversely affect patient outcomes. To improve patient engagement, healthcare systems must invest in strategies that address language barriers, enhance care coordination outside of the clinic, and foster greater patient education. These efforts would create a more inclusive and equitable healthcare environment, improving patient understanding and adherence while also fostering trust. By addressing these issues,

healthcare systems can reduce disparities and empower patients, families, and caregivers throughout the healthcare journey.

Inclusion of a parent advocate or expert would offer invaluable perspectives on patient experiences, especially regarding transitions from hospital care to home care and may reduce readmission rates. Beyond focusing solely on individual patients, healthcare must also consider broader public health dynamics and cultural sensitivity. Cultural practices and alternative medicines are often preferred in certain communities, yet traditional medicine is not always sufficiently responsive to these preferences. The development of MedTech should be informed by cultural considerations, ensuring that innovations align with the values and needs of diverse populations. This process should begin by actively listening to the public and incorporating their voices into the development process. MedTech, as a public good, has the potential to benefit a wide range of communities, including those who are not traditional patients.

Patient experience data (PED), patient-focused drug development (PFDD), and patient input in medical device development are poised to become cornerstone elements of our evolving healthcare systems. Regulatory agencies now mandate that new therapeutic products must not only demonstrate clinical efficacy but also meaningfully enhance patients' quality of life, substantiated through robust evidence that integrates patient perspectives at every stage of design, generation, and analysis. This marks a pivotal shift from historical rhetoric around patient-centricity to a genuine model of partnership, where patients and advocates assume equal and active roles in the drug development process.

In the United States, the Milken Institute's November 2022 report on "The Current Landscape of the Science of Patient Input" highlights the strategic importance of incorporating patient voices into medical innovation. The subsequent "Future of Health Summit" in December further explored the burgeoning potential for synergistic collaborations between nonprofit and for-profit entities in patient engagement research. These dialogues underscore a transformative opportunity to leverage

comprehensive patient insights, ultimately driving more effective solutions in the pediatric healthcare landscape, enhancing therapeutic outcomes, and fostering deeper engagement within the medical community.

A culturally sensitive approach to MedTech development could take many forms. For example, a discreet inhaler for self-conscious teens or efforts to incorporate caregivers' perspectives into pediatric device development can greatly enhance the usability and acceptance of MedTech solutions. Working with, rather than against, cultural norms can foster trust and increase the adoption of innovative healthcare solutions. Exploring ways to integrate alternative therapies, which are often trusted more in specific communities, could improve engagement and satisfaction with MedTech offerings.

Families increasingly want to make healthcare decisions from home, desiring more control over their health and the care of their children. According to a recent study conducted by Rennie Health, 85% of parents are interested in medical device technology when it can improve quality or ease of care for their children. Remarkably, 67% of Rennie patients indicated they could potentially resolve an in-person doctor's visit online if they had access to remote tools. To accelerate innovation in healthcare, it is crucial to champion technologies that simplify, rather than complicate, the patient journey. MedTech innovations must address core challenges in healthcare, such as inefficient workflows, outdated administrative burdens, and a lack of accessible, patient-friendly information. Supporting young startups, promoting research on co-morbidities, and improving opportunities for pediatric-focused innovations are essential steps in this process. Ultimately, patient engagement, language access, and health literacy tools must be prioritized. As the healthcare workforce expands, it is vital to create an environment that supports not only patients but also providers. By focusing on these areas, we can cultivate a healthcare system that truly serves patients, promotes meaningful provider support, and fosters long term, sustainable innovation.

VI. CONCLUSION

MedTech innovators must expand their vision to include diverse funding and partnerships with the FDA. The development process should incorporate culturally sensitive, patient- and family-centered approaches to designing healthcare technologies. Acknowledging the risks inherent in new models and ensuring that developers seek out experts who can collaborate on quantifying how the solutions tie into workflows, helps decision-making, and can discuss and iterate on the limitations and benefits of these models is crucial to long-term success. Collaboration with interdisciplinary teams through hackathons and innovation challenges is an excellent way to refine products and identify pressing needs. Additionally, writing policy advocacy letters and engaging in policy change efforts can accelerate the widespread adoption of innovative technologies. The 2024 OC Impact Conference highlighted the critical role academic innovators play in advancing translational health research.

The following strategies are recommended:

1. Explore ways to facilitate multicenter collaboration by implementing a unified standard for IRBs and consent processes that are transferable across sites. This approach could streamline the execution of clinical trials across multiple centers, enhancing collaboration and efficiency.
2. Provide guidance on integrating information technology (IT) systems with electronic health records to streamline workflows. Establish robust data security protocols to support the development of software as a medical device, particularly in specialized fields like neonatology.
3. While being located in a MedTech hub such as California and being affiliated with leading academic institutions offers certain advantages, it is personal networks and professional identities that play a pivotal role in advancing innovations from the laboratory to the clinic. Strengthening the role of academic partners in translational drug and device development is essential for improving the

success rates of new therapies. Academic institutions can contribute to this process by fostering collaboration between scientists and clinical researchers, establishing internal systems to scout promising projects, and involving scientists in critical decision-making.

4. Careful attention to technical feasibility, validity, regulatory pathways, intellectual property issues, and cost-effectiveness during early-stage assessments will streamline the transition from basic research to clinical applications, ultimately improving patient outcomes.

5. A formalized, comprehensive translational research process, spanning all clinical phases, is essential for success. This process requires substantial investment, specialized expertise, and long-term vision to ensure that the infrastructure supporting successful translational research is sustained. Despite the potential benefits of academic involvement in translational research, challenges remain. Securing stable funding for long-term infrastructure, creating incentive structures to promote high-risk, high-reward research, and the evolution of academic performance metrics to reward impactful projects are essential for advancing the translational pipeline. Early-stage collaborations between academia, biotechnology firms, and pharmaceutical companies are necessary to access expertise, foster innovation, and enhance efficiency.

The triple helix model, which emphasizes collaboration among academia, industry, and government, is a proven framework for advancing translational health research. Notably, the incorporation of medical research charities into this model could enhance its effectiveness, addressing some of the limitations currently faced.

A quadruple helix model, which includes a broader array of stakeholders, may offer a more comprehensive approach to advancing translational research. To address the challenges and improve

the success of translational research, academic institutions should focus on integrating basic scientists into translational centers, promoting interdisciplinary collaboration, and providing targeted incentives for early-stage research. Early concept assessments that consider the technical feasibility, regulatory pathways, and costs associated with a research program will ensure that promising discoveries are effectively translated into clinical solutions.

Moreover, fostering a culture of continuous learning and adaptation among MedTech innovators is essential for navigating the complexities of healthcare technology development. This includes not only embracing feedback from end-users but also engaging with community stakeholders, at the right time to ensure that innovations are relevant and responsive to diverse patient needs.

Encouraging mentorship programs that connect experienced innovators with emerging talent can also cultivate the next generation of leaders in MedTech, paving the way for innovative ideas that address gaps in current healthcare practices. In addition, a robust strategy for user education and training is vital to facilitate the adoption of new technologies. Establishing feedback loops where users can report their experiences will provide invaluable insights into how technologies can be refined post-launch to improve outcomes and tie into care workflows.

Ultimately, prioritizing educational outreach and support will ensure that healthcare technologies not only reach the market but also fulfill their potential in enhancing patient care and overall health outcomes. As the MedTech landscape evolves, aligning innovation efforts with patient needs and community values will be key to driving sustainable change and progress in research and healthcare.

LOOKING AHEAD

We stand at a pivotal moment to fundamentally reimagine healthcare delivery, shifting from legacy systems to an integrated model that prioritizes prevention, wellness, and community health.

This transformation presents a strategic opportunity to build efficient, technology-enabled care pathways while thoughtfully transitioning from outdated infrastructures that no longer serve our populations effectively. By leveraging advanced technologies, data analytics, and community-based approaches, we can create a healthcare ecosystem that emphasizes proactive wellness management, reduces care disparities, and optimizes resource allocation.

DECLARATIONS

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- Human Ethics and Consent to Participate declarations: Not applicable
- This manuscript does not report on or involve any animals, humans, human data, human tissue, or plants.
- This manuscript is in accordance with the Declaration of Helsinki.
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