MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Pathology Innovation Collaborative Community (PIcc)
Annual Meeting 2023

Unlocking the Potential of Digital Pathology and AI through Regulatory Science

June 27-28, 2023

MEET

SYNERGIZE

IMPACT

NAME :

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Agenda

Day 1 – Tuesday, June 27

Time	Speaker	Session
8:00 AM	Check-in/Breakfast	
8:30 AM	Welcome (MDIC and PIcc)	Andy Fish & Joe Lennerz
9:00 AM	**Session 1: Updates from Organizations and Initiatives related to DP/AI Moderated by Joe Sapiente**	
	Esther Abels, DPA	Digital Pathology Association (DPA) and DPA Foundation: Current scope of the work of the DPA and Foundation
	Doc de Baca, CAP	College of American Pathology (CAP): Pathology Innovation and Data Science
	Ji-Yeon Kim, API	Association for Pathology Informatics (API): Pathology Informatics – A Field or a New Practice?
	Susan Van Meter, ACLA	American Clinical Laboratory Association (ACLA) Updates
	Alex Kalof, ADASP	Association of Directors of Anatomic and Surgical Pathology (ADASP) Updates
	Panel Discussion for Session 1	Moderated by Joe Sapiente
10:20 AM	Coffee Break + Networking	
10:30 AM	Troy Tazbaz, FDA	FDA Talk 1: DHCoE Overview and Updates
11:00 AM	Fireside chat with Troy Tazbaz	Moderated by Jithesh Veetil
11:15 AM	Break	

11:30 AM	**Session 2: From Regulatory Science to Patients Moderated by Brittany McKelvey**	
	Mark Stewart, FOCR	Friends of Cancer Research (FOCR): Advancing Regulatory Science
	Hannah Mamuszka, Alva10	Value of Diagnostics in Healthcare
	Mariano de Socarraz, CorePlus	The Journey to Precision Pathology
	Mickey Williams, NIH	What Can We Learn From Other Technologies
	Joshua Greenlee, APPIA	Pre-analytics
	Panel Discussion for Session 2	Moderated by Brittany McKelvey
12:50 PM	Lunch	
1:00 PM	Key Note I: A Vision for Digital Pathology and AI - Thomas Fuchs, Paige	
1:30 PM	Q&A with Thomas Fuchs	Moderated by Joe Lennerz
2:00 PM	**Session 3: Research in The FDA: An Overview Moderated by Ed Margerrison**	
	Brandon Gallas, FDA (OSEL)	FDA Talk 2: Regulatory Science Projects in OSEL's Digital Pathology Program
	Alexej Gossmann, FDA (DIDSR)	FDA Talk 3: DIDSR AI/ML research program and gaps
	Ayobami Adebowale, FDA	FDA Talk 4: Predetermined Change Control Plan
	Panel Discussion for Session 3	Moderated by Ed Margerrison
03:45 PM	Coffee Break + Networking	

4:00 PM	**Session 4: Breakout Session Topics Moderated by Joe Lennerz**	
	Remote Work	Mike Isaacs Matthew Leavitt Doc de Baca
	PCCP	Emre Gulturk Kevin Schap Alexej Gossmann
	Statistics	Kim Blenman Gina Giannini Brandon Gallas
04:30 PM	Open Topic	Jeni Caldera Joe Lennerz
05:00 PM	Break	
05:30 PM	Networking Dinner	

Day 2 – Wednesday, June 28

8:15 AM	Welcome			
8:30 AM	**Breakout Session 1**			
	Remote work Matt Leavitt Mike Isaacs Doc de Baca Joe Sirintrapun	**PCCP** Emre Gulturk Kevin Schap Alexej Gossmann	**Statistics** Brandon Gallas Kim Blenman Gina Giannini	**Open topic** Jeni Caldera Joe Lennerz
9:15 AM	Create summary slide			
9:30 AM	Coffee Break + Networking + Rotate			
10:00 AM	Brief presentations by each breakout group			
	Vote on Projects			

10:30 AM	Keynote II: MedPerf Open and Standardized Benchmarking of Medical Artificial Intelligence - Alex Karargyris			
11:30 AM	**Breakout Session 2**			
	Remote work Matt Leavitt Mike Isaacs Monica de Baca Joe Sirintrapun	**PCCP** Emre Gulturk Kevin Schap Alexej Gossmann	**Statistics** Brandon Gallas Kim Blenman Gina Giannini	**Open topic** Jeni Caldera Joe Lennerz
	Create summary slide			
12:30 PM	Coffee Break + Networking + Rotate			
	Brief presentations by each breakout group			
	Vote to narrow down to 2 projects			
1:00 PM	Lunch break			
2:00 PM	**Final Breakout Session**			
	Topic 1	**Topic 2**		
	Create summary slide			
3:00 PM	Coffee Break + Networking + Rotate			
	Brief presentations by each breakout group			
	Vote			
3:30 PM	Discussion and Next Steps			
4:00 PM	Closing remarks	MDIC & PIcc		

Biographies

Andrew C. Fish

President and CEO

MDIC

Andrew Fish has extensive experience leading advocacy and policy organizations at the complex intersections of regulated business, health care, science, technology, law, media, and politics. He has particular expertise in medical technology matters ranging from innovation and regulation to reimbursement and health care delivery. Fish previously held multiple roles at AdvaMed, the Advanced Medical Technology Association, including Chief Strategy Officer, Executive Director of the AdvaMed Center for Digital Health, Executive Director of AdvaMedDx, and Head of Sector Initiatives. Prior to AdvaMed, Fish was Senior Vice President of Legal and Government Affairs, General Counsel, and Secretary for the Consumer Healthcare Products Association (CHPA), representing manufacturers of non-prescription medicines. Mr. Fish also led the American Cancer Society's federal lobbying team as the Senior Director of Federal Government Relations. Earlier in his career, Fish served in the Senate-confirmed post of Assistant Secretary of Agriculture for Congressional and Intergovernmental Affairs after working as a deputy chief counsel and professional staff member for the U.S. Senate Agriculture Committee. Fish holds a BA from Yale University and a JD from Stanford Law School.

Jochen Lennerz, MD, PhD

Medical Director, Center for Integrated Diagnostics

Massachusetts General Hospital

Dr. Lennerz is board certified by the American Board of Pathology and the American Board of Medical Genetics. He joined the Massachusetts General Hospital Department of Pathology and Center for Integrated Diagnostics as a staff pathologist in 2014, and is an assistant professor at Harvard Medical School. Dr. Lennerz trained as a pathologist assistant in Berlin, Germany in 1994 and studied both medicine and molecular medicine at the University of Erlangen, Germany where he also received his MD and PhD. He completed his residency training in anatomic pathology in 2008, and a fellowship in molecular genetic pathology in 2009 at Washington University in St. Louis, MO. After completing a two-year gastrointestinal and liver pathology fellowship at Massachusetts General Hospital in 2011, he led a research group on biomarkers in lymphoma at Ulm University, Germany. His interests are tissue-based biomarkers, and financial sustainability of molecular genetic diagnostics. Early in 2015 Dr. Lennerz joined the Cancer Center's physician staff at Mass General, and began presenting at the Cancer Center Grand Rounds.

Esther Abels

CEO and Founder

SolarisRTC LLC

After having been a management team and C-suite member responsible for contribution to the overall business strategy and building up PharmaServices Esther started her own advisory company SolarisRTC in 2023.

Esther Abels has a background in business strategy, commercialization, bridging R&D, proof of concept, socio / health economics and pivotal clinical validation studies used for registration purposes in different geographies, for both pharma and biotech products. She has a wealth of regulatory, clinical and quality experience specializing in bringing products to clinical utility. She played a crucial role in getting Whole Slide Imaging devices reclassified in USA.

Esther drives efforts for reimbursement in Digital Pathology and collaborations with different Pathology Associations. In 2022 she was the president for the Digital Pathology Association (DPA) and she has chaired the DPA Regulatory and Standards Taskforce and facilitates FDA collaborations to drive regulatory and standard clarifications for interoperability and computational pathology in the field of digital pathology.

She is also a co-founder of the Alliance for Digital Pathology / Pathology Innovation Collaborative Community where she co-leads the reimbursement workgroup.

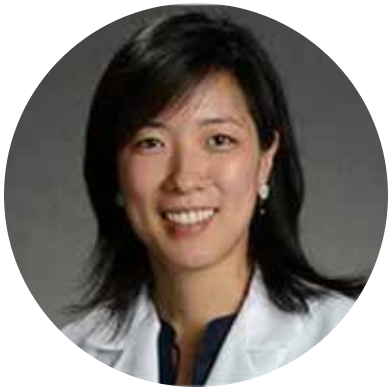
Esther holds a MSc in Biomedical Health Science from Radboud University Nijmegen.

M. E. de Baca (Doc), MD, FCAP

VP for Medical Affairs

Sysmex America, Inc

Dr. de Baca, VP for Medical Affairs at Sysmex America, Inc, has directed high complexity hematopathology services, served as laboratory medical director of College of American Pathologists (CAP) accredited high complexity laboratories, and has been affiliated with academic teaching centers (as a community pathologist). She serves on the Board of Governors, Chairs the Council on Informatics and Pathology Innovation, and is a member of the Executive Committee and the Council on Education. In Informatics, she is most interested in structured disease reporting, healthcare data management, clinical laboratory interoperability, decision support, and SNOMED-CT. Prior activities with the CAP include SNOMED International Editorial Board, founding co-chair of the CAP Pathology Electronic Reporting Taskforce (PERT), Cancer committee, DIHIT, and the House of Delegates; she has served as CAP liaison to NAACR and to SNOMED International. Dr de Baca is a Past President of the Association for Pathology Informatics and served on CLIAC Advisory Committee. Board certified in AP/CP and hematopathology (ABP) and in Ophthalmology (Land Brandenburg/FRG), she continues to practice at Pacific Pathology Partners in Seattle, WA and is a Co-Founder of MDPath, LLC, which offers pathology consulting services.



Ji Yeon Kim, MD MPH

Physician Director, Esoteric Chemistry, Immunology, Special Coagulation, Lab Informatics

Kaiser Permanente

Dr. Ji Yeon Kim received her medical degree from Harvard Medical School and completed her master's degree in public health at Harvard School of Public Health. She completed her residency in clinical pathology and fellowships in medical microbiology and pathology informatics at Massachusetts General Hospital before moving to Los Angeles. As Physician Director of Laboratory Informatics at Kaiser Permanente Southern California for the past 11 years, Dr. Kim has oversight over the information systems supporting clinical lab testing in 15 hospitals, 3 Regional Reference Labs, as well as multiple outpatient draw centers, for over 4.8 million members. She chairs several committees to facilitate standardized, evidence-based workflows and EMR/LIS changes that align with the organization's clinical and strategic goals, and reviews new technology investments on behalf of the laboratory system. This year, Dr. Kim is the acting president of the Association for Pathology Informatics (API), a volunteer, non-profit organization dedicated to promoting the field of pathology informatics as an academic and clinical subspecialty of pathology, through education, advocacy, standards development, and research.

Susan Van Meter

President

American Clinical Laboratory Association (ACLA)

ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. Prior to joining ACLA in 2022, Van Meter was Executive Director of AdvaMedDx, representing manufacturers of in vitro diagnostic (IVD) clinical tests. Previously, she held roles as Senior Vice President of Federal Relations at the Healthcare Association of New York State and in the Centers for Medicare & Medicaid Services' Office of Legislation. Van Meter holds a B.A. from Villanova University and an M.A. from Boston University.

Alexandra Kalof , MD

Division Chief, CLIA Laboratory Director of Anatomic Pathology

University of Vermont Medical Center

Dr. Alexandra Kalof is the Division Chief and CLIA Laboratory Director of Anatomic Pathology at the University of Vermont Medical Center in Burlington, VT and Professor in Pathology and Laboratory Medicine at the Larner College of Medicine at the University of Vermont. She completed her Anatomic and Clinical Pathology residency at the University of Vermont Medical Center and fellowship in Surgical Pathology at Stanford University in Palo Alto, CA. While a generalist at heart, Dr. Kalof subspecializes in Bone and Soft Tissue and Gynecologic Pathology. An officer and council member of Association of Directors of Anatomic and Surgical Pathology (ADASP), she has a passion for laboratory management with a specific focus on organizational structures, LEAN process improvement, and change management.

Joseph Sapiente

Vice President of Clinical Science and Technology

MDIC

Joseph joins MDIC with over 37 years of medical device experience in quality and regulatory compliance, product registration, continuous improvement and new product development and innovation. Joseph has led Quality Operations and Compliance at Medtronic. He has held executive leadership roles in quality, regulatory, clinical affairs and professional medical education and training at Covidien, Tyco HealthCare and US Surgical. He led the Quality Begins with Me culture initiative for Covidien and the enterprise – wide QBWM role out at Medtronic.

Before joining MDIC, Joseph was the Vice President of Quality Assurance and Regulatory Affairs, Surgical, Breast, Skeletal Health, for Hologic, Inc., manufacturers of life saving and life enhancing technologies in women's health including, Breast Heath, Skeletal, Gyn Surgical and Diagnostic Solutions. In addition to his role at Hologic, Joseph served as Industry Chair and Steering Committee Chair of MDIC's Case for Quality collaborative community and AdvaMed Case for Quality Working Group. Joseph has been an active member of the Case for Quality program at MDIC since 2012.

Troy Tazbaz

Director, DHCoE

FDA

Troy Tazbaz is Director of Digital Health Center of Excellence (DHCoE) at FDA. DHCoE within the Center for Devices and Radiological Health (CDRH) is responsible for envisioning a future of safe and effective healthcare delivery with a focus on advancing public health goals with the use of technology. Troy Tazbaz is responsible for providing leadership in technology evaluation and integration into clinical care, policy development to establish digital health guidelines, and strategic public-private institution partnerships.

Prior to joining FDA, Mr. Tazbaz was at Oracle for 11 years, holding a variety of technical and business responsibilities in building and scaling the cloud business as Senior Vice President of Industry Business Unit Strategy & Operations.

Jithesh Veetil, PhD

Senior Program Director, Digital Health & Technology

MDIC

Dr. Jithesh Veetil, PhD serves as the Senior Program Director of Digital Health and Technology portfolio at the Medical Device Innovation Consortium (MDIC). His prime focus at MDIC is to aid in the development of regulatory science resources and regulatory grade tools working collaboratively with government and industry stakeholders in an effort to advance solutions that promote patient access to innovative medical technologies. Jithesh's current portfolio at MDIC includes projects in Computational Modeling & Simulation (CM&S), Medical Device Cybersecurity, Medical Extended Reality (MXR), Software as/in Medical Devices (SaMD/SiMD), and Digital Pathology.

Previously, Jithesh worked with Global Biological Standards Institute (GBSI), a Washington DC based non-profit as its Scientific Program Manager, leading the development and implementation of multiple programs on science policy, communications, and advocacy, including those related to cell line authentication, antibody validation, and reproducibility in biomedical research and development. Jithesh has extensive experience in designing and development of programs towards modernizing scientific workforce and practices by building academic-industrial-nonprofit collaboration through his work at National Institutes of Health (NIH) campus as the Lead Scientist and Program Manager for the Foundation for Advanced Education in the Sciences (FAES). Jithesh also served as the Operations Manager for Preludesys Inc., working with international clientele from medical, IT, insurance and paralegal organizations on medical/healthcare data management. Jithesh completed his PhD in Biomedical Engineering at University of Arkansas, Fayetteville, AR, followed by postdoctoral fellowship at NIH. He has published numerous peer-reviewed manuscripts, reviews and book chapters.

Mark Stewart, PhD

Vice President, Science Policy

Friends of Cancer Research

Mark Stewart serves as a Vice President, Science Policy at Friends of Cancer Research (Friends). Friends is an advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. For more than two decades, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible.

At Friends, Mark leads the development and implementation of the organization's research and policy agenda as well as overseeing the conduct of research projects to inform ongoing policy discussions. Mark establishes unique partnerships to help develop innovative policy proposals and consensus-driven solutions to address challenges and accelerate cancer drug development. He regularly participates in policy discussions and meetings throughout the year to help catalyze meaningful change for oncology healthcare.

Prior to joining Friends, Mark worked at the National Academies of Sciences, Engineering, and Medicine. At the Academies, he assisted with a congressionally mandated study that resulted in the report titled Ovarian Cancers: Evolving Paradigms in Research and Care. This report identified gaps in ovarian cancer knowledge and care, and established science and policy recommendations to overcome these gaps. Mark also assisted the National Cancer Policy Forum.

Mark has had the honor to serve on several membership and working group committees, including serving as chairperson for the Associate Member Council of the American Association for Cancer Research (AACR) and member of the Drug Information Association Program Planning Committee.

Mark Stewart received his PhD in cancer biology from the University of Alabama at Birmingham.

Hannah Mamuszka

CEO, Founder

Alva10

Hannah Mamuszka is Founder and Chief Executive Officer at Alva10, which she founded in 2015 to spur change in healthcare to allow more patients better access to diagnostic technology. Hannah's career has spanned the laboratory and business sides of healthcare in both the pharma and diagnostics industries. Prior to Alva10, Hannah was VP of Exosome Diagnostics (acquired by BioTechne), where she led some of the earliest deals in the liquid biopsy space. Earlier in her career, she was Global Director of Pharmaceuticals Services for Oncotech, and then by acquisition, Exiqon (acquired by QIAGEN), where she built the Pharmaceutical Services and Companion Diagnostics business in the US, Europe, and ROW. Prior to her time in diagnostics, she worked on the IND

submission for VelcadeTM at Millennium Pharmaceuticals (acquired by Takeda). She started her laboratory career at the National Institutes of Health, holding laboratory positions in both the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Disease (NIAID). Hannah is a frequent speaker and writer on how to drive change in healthcare, and is on the editorial board for the Journal of Precision Medicine, where she also writes a regular column on the challenges of implementing change in medicine. Hannah serves on the Board of Directors for Bionano Genomics (BNGO) and the University of North Carolina's Carolina Health Informatics Program (CHIP).

Mariano de Socarraz

CEO

CorePlus

Mariano de Socarraz is a healthcare industry leader, innovator, and entrepreneur with over 40 years of experience. Mr. de Socarraz serves as the CEO, CorePlus Servicios Clínicos y Patológicos, L.L.C., since founding the company in 1996. CorePlus is a specialized anatomic pathology and clinical laboratory company which provides services to medical practices, health centers, ambulatory surgical centers, multi-specialty group practices, and healthcare facilities. In addition, Mr. de Socarraz is President and Founder of Syndeo, a healthcare IT company dedicated to developing solutions for anatomical and clinical laboratories.

Mr. de Socarraz has been a global pioneer in the planning, development and implementation of digital pathology. He has led and funded the team at CorePlus to successfully convert the laboratory's traditional histology practice (H&E, immunohistochemistry, special stains) to a full digital environment including remote sign-out since January 1st, 2020. In addition, he led CorePlus in becoming the first pathology organization in the Americas to operationalize the use of Artificial Intelligence (AI) in prostate cancer beginning June 1st, 2020. At present, he continues to lead the application of AI for the diagnosis of other health conditions. His contributions have been recognized by being selected to serve as a Member of the Board of Directors of the Digital Pathology Association.

Throughout his career, Mr. de Socarraz has served as an Executive in several companies, including as Vice-President, General Manger for Sonics International, a wholly owned subsidiary of Diasonics, Inc. from 1980 to 1984. He also served as Director of Business Development/Southeast for Medical Resources from 1985 to 1988, a leading provider of specialty imaging services. From 1988 to 1998, Mr. de Socarraz was the President of Imaging Healthcare, which specialized in the distribution of urological healthcare products and services throughout the Southeastern United States and Latin America.

Mr. de Socarraz holds multiple professional registries in the ARRT (American Registry of Radiologic Technologist) and RDMS (Registered Diagnostic Medical Sonographer). Mr. deSocarraz is degreed in Radiologic Technology (AS), International Marketing (BS) and has completed course work towards a Masters in Business Administration (MBA) Degree with a specialization in Health Care Administration.

P. "Mickey" Williams, Ph.D.

Director, Molecular Characterization Laboratory
Leidos Biomedical Research, Inc.
Frederick National Laboratory for Cancer Research

The Molecular Characterization Laboratory (MoCha) was established by the National Cancer Institute (NCI), Division of Cancer Treatment and Diagnosis (DCTD), to focus on development of state-of-the-art molecular technologies for clinical research. Laboratory goals are to assist in the development and application of well-characterized and validated clinical assays to support cancer patient management and clinical research. MoCha has played a role in many clinical trials including the development and implementation of analytically validated NGS assays for selection of patients for clinical trials (e.g. NCI-MATCH, Pediatric MATCH, NCI-MPACT, iMATCH and soon MyeloMATCH). MoCha provides genomic characterization for the NCI's Patient Derived Model Repository. Other activities include development of reference and quality control materials for use in clinical assays. MoCha is actively pursuing development and implementation of circulating tumor DNA and single cell sequencing assays.

Mickey has been active in the use of molecular technologies for drug-target discovery. During his thirteen years at Genentech, he developed novel assays to support clinical studies and discover new therapeutic targets. He was the author of the first quantitative "real-time" PCR papers and contributed to the development of this powerful technology. Prior to joining FNLCR in 2010, he was a senior research group leader at Roche Molecular Diagnostics. While at Roche, he led the research effort and managed two large multi-national clinical assay studies: The MILE Study (microarray innovations in leukemia), and a collaboration with the LLMPP (leukemia and lymphoma molecular profiling project). He also initiated 2 projects that have subsequently been approved by the FDA as IVD tests. He has published over 50 manuscripts and is an inventor on over 30 issued U.S. Patents. Mickey received his Ph.D. from the University of Virginia.

Joshua Greenlee, MBA, IASSC CBB™, HT/HTL(ASCP)cm

Senior Product Manager & Laboratory Workflow/ Productivity Strategist
Sakura Finetek USA, Inc

Joshua Greenlee also serves on the board for APPIA (Anatomical Pathology Patient Interest Association). He has more than 20 years of laboratory experience, primarily in anatomic pathology. He holds a Bachelor of Science in Biology, Master of Business Administration specializing in Project Management, and is dual ASCP certified as an HT/HTL(ASCP)cm. In addition to laboratory work, he spent 4 years working in the NAACLS accredited histology program at Phoenix College. He joined Sakura Finetek USA, Inc., in 2015. With his current position, as an IASSC Certified Black Belt in Lean Six Sigma, Joshua focuses on workflow and implementation of innovative automation solutions in anatomic pathology.

Brittany Avin McKelvey, PhD

Director, Regulatory Affairs

Friends of Cancer Research

Brittany Avin McKelvey serves as the Director of Regulatory Affairs at Friends of Cancer Research (*Friends*). *Friends* is an advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. Brittany supports the development and implementation of the organization's research and policy agenda. She leverages her patient advocacy and scientific background to generate scientific evidence and policies to advance progress in oncology care. She collaborates with diverse stakeholders to inform policy objectives and execute evidence-based research projects.

Prior to joining *Friends*, Brittany worked for the American Cancer Society Cancer Action Network (ACS CAN) as a Policy Fellow after receiving her PhD in molecular biology and genetics from Johns Hopkins University School of Medicine. As a childhood cancer survivor, Brittany is actively involved as a patient research advocate with multiple organizations.

Thomas Fuchs, Dr. Sc

Founder and Chief Scientist

Paige

Dr. Thomas J. Fuchs is the Founder and Chief Scientist at Paige. He is a pioneer in the groundbreaking field of computational pathology whose inventions led to the first FDA-approved AI-based pathology product, Paige Prostate. Dr. Fuchs was named one of the Top 100 AI Leaders in Drug Discovery and Advanced Healthcare in 2019. He is also the Dean of Artificial Intelligence and Human Health and Co-Director of the Hasso Plattner Institute for Digital Health at the Icahn School of Medicine at Mount Sinai.

Previously, he was Associate Professor for Machine Learning at Weill-Cornell University, Director of the Warren Alpert Center for Digital and Computational Pathology at Memorial Sloan Kettering Cancer Center and Research Technologist at NASA's Jet Propulsion Laboratory. Dr. Fuchs holds a Doctor of Sciences from ETH Zurich in Machine Learning and a MS in Technical Mathematics from Graz Technical University in Austria.

Edward Margerrison

Director, OSEL

FDA

Ed is the Director for the Office of Science and Engineering Laboratories (OSEL) at the Center for Devices and Radiological Health, US FDA. The Office is responsible for providing technical expertise and analyses in support of the regulatory processes within CDRH. In addition, the c300 scientists and engineers engage in representing the Agency on International standards organizations, provide scientific guidance for policy, and "futureproof" the Center for technologies making their way into novel medical devices.

Previously, he was President and CEO of Ortho Regenerative Technologies, a biotech startup based in Montreal, developing novel biomaterial approaches to surgical soft tissue repair. During this appointment, Ed steered the company to listing on the Canadian stock exchange, and started the regulatory process for the technology with the Center for Biologics at FDA.

He has also held senior positions at Zimmer Biomet (Vice President of Biologics), where he was primarily responsible for the cartilage repair business, has held other positions in both the pharmaceutical (Akela Pharma) and Orthopedics (Smith & Nephew) industries.

He graduated in Biochemistry from the University of Oxford and gained his PhD in Molecular Genetics from St George's Hospital Medical School in London UK, where he studies the mechanisms of resistance to quinolone antibiotics.

Brandon D. Gallas, PhD

Research Mathematical Statistician

FDA

Brandon D. Gallas provides mathematical, statistical, and modeling expertise to the evaluation of medical imaging devices at the FDA. His main areas of research are image quality, computer-aided diagnosis, imaging physics, and the design, execution, and statistical analysis of reader studies. Recently, he has been investigating pathologist performance and agreement using whole slide imaging devices and the microscope. These studies are enabled by an evaluation environment that registers the digital images to the glass slides. Dr. Gallas also participates in the Pathology Innovation Collaborative Community, a regulatory science initiative to harmonize and standardize digital pathology processes to speed up innovation to patients.

Alexej Gossmann

Staff Fellow

FDA

Alexej Gossmann is a Staff Fellow at the U.S. Food and Drug Administration (FDA), CDRH/OSEL Division of Imaging, Diagnostics, and Software Reliability, where he splits his time evenly between regulatory work and academic research. His current research interest is in topics adjacent to performance evaluation of medical artificial intelligence (AI) and machine learning (ML) algorithms, with peer-reviewed publications in journals and venues such as JASA, IEEE TMI, JAMIA, SIAM JMDS, Biometrics, UAI, SPIE MI, MED-NeurIPS, etc. Since joining the FDA in 2018, Alexej has participated in the regulatory review of over 100 submissions of AI/ML-based medical devices/software. Alexej received his PhD degree in 2018 from the interdisciplinary Bioinnovation Program at Tulane University, New Orleans, LA, coming from a prior background in mathematics and statistics.

Ayobami Adebowale

Biomedical Engineer

FDA

Ayobami Adebowale is a biomedical engineer working in Digital Health Policy for the Digital Health Center of Excellence at the Food and Drug Administration's Center for Devices and Radiological Health. She works on strategic policy initiatives, including developing and implementing new policy and regulatory approaches for the use of Artificial Intelligence and Machine Learning in medical devices. She is also involved in efforts to increase the use of regulatory science tools to advance health equity. Previously, Ayobami was a Lead Reviewer in the Office of Cardiovascular Devices in the Office of Product Evaluation and Quality. Prior to joining the agency, she earned her Master of Engineering in biomedical engineering from Cornell University.

Michael Isaacs

Director of Clinical Informatics and Business Development

Washington University School of Medicine

Mike Isaacs is the Director of Clinical informatics and Business Development at Washington University in the Department of Pathology and Immunology. He has a computer science background and over 25 years of experience in supporting Information Technology in the laboratory, which has provided him with the experience to identify the informatic needs of the department. Mike has been involved with Digital pathology for over ten years and has developed multiple digital workflows to take advantage of technology in the laboratory. For

the last 4 years, he has focused on building and integrating Digital Pathology Solutions for Internal use and for our Outreach Client business at WU/BJC hospital. His primary interest is providing a strategic vision for the implementation of Digital Pathology for the BJC HealthCare system, which consists of 15 hospitals in two states. He is currently on the DPA board of Directors and sits on the foundation and program committees of the DPA.

S. Joseph Sirintrapun, M.D., FASCP, FCAP

Director of Pathology Informatics

Memorial Sloan Kettering Cancer Center

S. Joseph "Joe" Sirintrapun, MD, is an Associate Attending, Director of Pathology Informatics, and a member lead of the Warren Alpert Center for Computational Pathology at Memorial Sloan Kettering Cancer Center (MSKCC). He is also the past 2021 president of the Association for Pathology Informatics (API).

As a director and the 2021 ex-API President, Joe is a recognized leader and expert in digital and computational technologies. His work focuses on the "operationalization" of digital pathology, AI, and advanced diagnostic technologies. Likewise, Joe actively participates in many other national committees to enable digital and computational technologies and data initiatives to steer national strategic direction and policy.

Joe is also a clinically practicing surgical pathologist with expertise in genitourinary tumors. Thus, his perspectives in informatics, computational pathology, and clinical practice confer a nuanced understanding for regulatory approaches on emerging technologies and their integration into clinical practice.

Matthew O. Leavitt, MD

Founder & Chairman of the Board

LUMEA | DDx Foundation

Matthew O. Leavitt, MD spent his first two decades living in rural Southern Utah, Northern England and Romania. After medical school at Dartmouth, he completed residency and 2 subspecialty pathology fellowships at Stanford University Hospitals. Following training, he worked in Intermountain Healthcare's urban hospitals, serving a few years as department chair, and overseeing lab diagnostics for patients referred from extremely remote locations. It was from that perspective that he first saw digital pathology's potential to provide all people with access to higher quality care. In 2014 Dr. Leavitt stepped away from the hospital-based practice to establish Lumea Inc., a leading digital pathology platform. At Lumea he pioneered not only multiple patented lab technologies, but also a more affordable pathology service delivery model, the digital histology center (DHC). In 2020, he left Lumea to further expand the "virtual pathology" practice model within PathNet, a network of digital pathology practices providing anatomic pathology services to clinics and community hospitals in under-served communities throughout the United States. PathNet

pathologists, operating out of three DHCs, now serve hundreds of clinics and several community hospitals in over 30 states.

Drawing on these unique experiences and perspectives, Dr. Leavitt is now focused on harnessing the potential of patient health data to improve care for individuals no matter where they happen to live. Serving on boards for the Open Pathology Education Network (OPEN) and Digital Diagnostics Foundation (DDx) he seeks to align interest of technology companies, and healthcare service providers in efforts to improve safe and efficient exchange of health data.

Dr. Leavitt and his wife Louise McConkie live in Michigan, but spend much of their lives trying to keep up with their children who now live all over the country.

Emre Gültürk

VP of Regulatory Affairs and Quality Systems

Paige

Emre Gulturk is the Vice President of Regulatory Affairs and Quality Systems at Paige, where he is leading Paige's worldwide regulatory and compliance initiatives. Emre has over a decade of experience in digital health, including leading marketing authorizations for the first digital therapeutic in the treatment of ADHD, first diagnostic AI in dentistry, and most recently the first diagnostic AI in digital pathology. Emre earned an MSc from University of Minnesota, and a Bachelor of Science degree in Materials Science from METU in Turkey.

Kevin Schap, MScBMI

Senior Manager, AI & Data Standards Initiatives

College of American Pathologists (CAP)

Kevin Schap received his master's degree in biomedical Informatics from the University of Chicago. He has been with the College of American Pathologists (CAP) in multiple roles since 2006, with his most recent being Senior Manager, AI and Data Standards Initiatives. Kevin acts as committee staff for CAP's Informatics Committee, Digital and Computational Pathology Committee, and Artificial Intelligence Committee. Each committee leads a variety of projects that include education, advocacy, implementation, and standardization, as well as serving as subject matter experts for other CAP initiatives. In addition to his committee management responsibilities, he also serves as the engagement lead for the CAP's In Vitro Diagnostic data quality assurance contract awarded through the FDA's Broad Agency Announcement Program.

Dr. Kim RM Blenman, PhD, MS

Assistant Professor

Yale University

Dr Blenman is an Assistant Professor of Medicine in the Yale School of Medicine, Department of Internal Medicine, Section of Medical Oncology, and the Yale Cancer Center. Dr Blenman is also an Assistant Professor of Computer Science in the Yale School of Engineering and Applied Science, Department of Computer Science. She earned a bachelor's in chemistry, a master's in clinical chemistry, and a doctorate in immunology from the University of Florida, Gainesville, Florida. Her research at that time focused on the autoimmune disease Systemic Lupus Erythematosus. She also has a certificate in Drug Development and Regulatory Sciences from the University of California San Francisco. She had the privilege of learning and working on drug discovery and clinical development at Procter & Gamble's Pharmaceutical division as a senior scientist and as a global research director for the autoimmune diseases Inflammatory Bowel Disease and Irritable Bowel Syndrome. She re-entered academia as a traditional Postdoctoral Fellow at the City of Hope Comprehensive Cancer Center in Duarte, California. During her fellowship, she uncovered a potential use for B cells in predicting metastasis and disease-free survival in breast cancer patients and pursued her passion of computer science. Dr Blenman's current interest is in clinical research, software development, therapeutic development, and health disparities. Her disease focus areas are cancer and autoimmunity with a special interest in the therapy-induced toxicity (treatment emergent adverse events (TEAEs)) bridge between the two disease areas.

Gina Giannini-Gwynn

Regulatory Affairs Lead of Digital Health/Digital Pathology

Verily

Gina is a Regulatory Affairs professional with a broad experience of over 15 years in the medical device and in vitro diagnostic device industries including digital health and digital pathology. Capitalizing on rigorous scientific training to analyze clinical data and published research evidence for the determination of global regulatory and clinical strategies.

Jenifer Caldara

Technical Sales Manager, Americas

Visiopharm

Jeni is an innovative digital pathology professional that specializes in AI-based image analysis and implementation. She is passionate about the role that AI may play in the clinical workflow and getting these tools into the hands of the pathologist within their existing systems. Currently, Jeni is the Technical Sales Manager for the Americas at Visiopharm and also serves as their Translational Specialist, where she collaborates closely with experts in the field of digital pathology.

Alexandros Karargyris

Chair

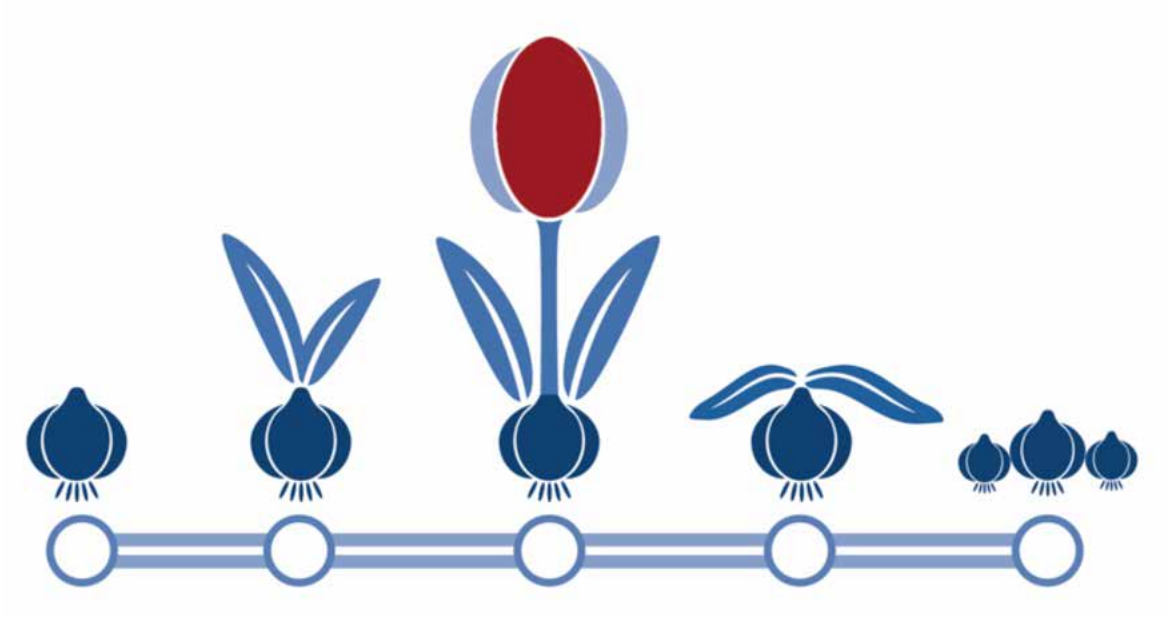
MLCommons

Alexandros Karargyris leads the medical working group at MLCommons. The group has a mission to provide neutral benchmarking and best practices for Medical AI in an effort to circumvent negative effects of AI. In its short life span the group has grown to already support the largest federation of brain tumor segmentation as well as to plan its prospective AI studies. Previously he worked as a research lead at IHU Strasbourg in projects related to applications in the intersection of surgery and AI. He also worked as a researcher at IBM and NIH for more than 10 years. His research interests lie in the space of medical imaging, machine learning and mobile health. He has contributed to healthcare commercial products and imaging solutions deployed in under-resourced areas. His research has been published in peer-reviewed journals and conferences.

About Us

Pathology Innovation Collaborative Community (PIcc)

A collaborative community with FDA participation; Convened by Medical Device Innovation Consortium (MDIC)



PIcc is a regulatory science initiative that aims to facilitate innovations in pathology as well as advance safety and effectiveness evaluation, and to harmonize approaches to speed delivery to patients using collaborative, pre-competitive approaches. The collaborative community (PIcc) is open to all stakeholders, public or private, including, but not limited to, academia, industry, health care providers, patients and advocacy groups. Recognized by FDA as a "collaborative community" in late 2020, PIcc, already completed numerous regulatory science projects through 9 working groups that encompasses the entire life cycle and diverse topics related to digital pathology products.

Current FDA Liaison for PIcc: Brandon Gallas, CDRH

FDA Executive FDA Sponsor: Edward Margerrison, CDRH

To learn more and join PIcc, visit https://pathologyinnovationcc.org/
OR scan here

Code of Conduct: The Pathology Innovation Collaborative Community

Our Pledge

We as members, contributors, and leaders pledge to make participation in the Alliance for Digital Pathology, and all applicable sub-committees, a harassment-free experience for everyone, regardless of age, body, size, visible or invisible disability, ethnicity, sex characteristics, gender identity and expression, level of experience, education, socio-economic status, nationality, personal appearance, race, religion, or sexual identity and orientation. We pledge to act and interact in ways that contribute to an open, welcoming diverse, inclusive, and healthy community including.

Be friendly, humble, and patient.

Be considerate. Your work will be used by other people, and you in turn will depend on the work of others. Any decision you take will affect users and colleagues, and you should take those consequences into account when making decisions. Remember that we're a world-wide community, so you might not be communicating in someone else's primary language.

Be respectful. Not all of us will agree all the time, but disagreement is no excuse for poor behavior and poor manners. We might all experience some frustration now and then, but we cannot allow that frustration to turn into a personal attack. It's important to remember that a community where people feel uncomfortable or threatened is not a productive one. Members of the Alliance for Digital Pathology should be respectful when dealing with other members as well as with people outside the Alliance community.

Be careful in the words that you choose. We are a community of professionals, and we conduct ourselves professionally. Be kind to others. Do not insult or put down other participants. Harassment and other exclusionary behavior aren't acceptable.

Our Standards

Examples of behavior that contributes to a positive environment for our community include:

- Demonstrating empathy and kindness toward other people
- Being respectful of differing opinions, viewpoints, experiences and approaches
- Giving and gracefully accepting constructive feedback
- Accepting responsibility, apologizing to those affected by our mistakes, and learning from the experience
- Focusing on what is best not just for us as individuals, but for the overall community
- Working collaboratively across institutions and countries
- Being transparent about potential conflicts of interest
- Giving attribution and crediting authors of scientific work

Examples of unacceptable behavior include:

- Public or private harassment
- Publishing others' personal information, such as a physical or email address, without their explicit permission
- Trolling, insulting, personal or political attacks
- Other conduct which could reasonably be considered inappropriate in a professional setting

Enforcement Responsibilities

Alliance and committee leaders are responsible for clarifying and enforcing our standards of acceptable behavior and will take appropriate and fair corrective action in response to any behavior that they deem inappropriate, threatening, offensive, or harmful.

Alliance and committee leaders have the right and responsibility to remove, edit, or reject comments, proposals, and other contributions that are not aligned to this Code of Conduct, and will communicate reasons for moderation decisions when appropriate.

Scope

This Code of Conduct applies within all Alliance for Digital Pathology spaces, and also applies when an individual is officially representing the Alliance in public spaces. Examples of representing our community include using an official e-mail address, posting via an official social media account or website, or acting as an appointed representative at an online or offline event.

Enforcement

Instances of abusive, harassing, or otherwise unacceptable behavior may be reported to the community leaders responsible for enforcement (feedback@digitalpathologyalliance.org).

All complaints will be reviewed and investigated promptly and fairly. All Alliance leaders are obligated to respect the privacy and security of the reporter of any incident.

Enforcement Guidelines

Alliance leaders will follow these Alliance Impact Guidelines in determining the consequences for any action they deem in violation of this Code of Conduct:

1. Correction

- Alliance Impact: Use of inappropriate language or other behavior deemed unprofessional or unwelcome in the community.
- Consequence: A private, written warning from community leaders, providing clarity around the nature of the violation and an explanation of why the behavior was inappropriate. A public apology may be requested.

2. Warning

- Alliance Impact: A violation through a single incident or series of actions.
- Consequence: A warning with consequences for continued behavior. No interaction with the people involved, including unsolicited interaction with those enforcing the Code of Conduct, for a specified period of time. This includes avoiding interactions in community spaces as well as external channels like social media. Violating these terms may lead to a temporary or permanent ban.

3. Temporary Ban

- Alliance Impact: A serious violation of community standards, including sustained inappropriate behavior.
- Consequence: A temporary ban from any sort of interaction or public communication with the community for a specified period of time. No public or private interaction with the people involved, including unsolicited interaction with those enforcing the Code of Conduct, is allowed during this period. Violating these terms may lead to a permanent ban.

4. Permanent Ban

- Alliance Impact: Demonstrating a pattern of violation of community standards, including sustained inappropriate behavior, harassment of an individual, or aggression toward or disparagement of classes of individuals.
- Consequence: A permanent ban from any sort of public interaction within the community.

ATTRIBUTION

This Code of Conduct is adapted from the Contributor Covenant, version 2.0 and the Django Code of Conduct. All content on this page is licensed under a Creative Commons Attribution license.

MDIC

Driving innovation in medical technologies

About MDIC

Founded in 2012, the Medical Device Innovation Consortium (MDIC) is the first publicprivate partnership created with the sole objective of advancing medical device regulatory science throughout the total product life cycle.

MDIC's mission is to break down barriers in the medical technology life cycle to accelerate innovation and adoption of safe, effective, and high-quality medical technologies. The consortium brings together medical technology manufacturers, researchers, regulators, payers, patients, and health care providers as trusted collaborators to solve complex challenges in the scientific and technical disciplines that propel medical technology development, approval, adoption, and access.

MDIC's work improves regulatory pathways, advances medical device quality, enhances patient safety and access, and facilitates the development of better evidence for approval, coverage, and utilization decisions.

MDIC's initiatives focus on four areas:

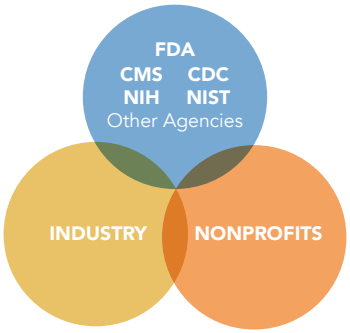
Clinical Science – Address the biggest barriers to collecting adequate clinical evidence in the support of new medical technology by creating blueprints for innovative clinical trials techniques, developing standards and metrics for effective clinical trial designs and encouraging the collection of adequate and appropriate clinical and patient preference data.

Digital Health & Technology – Fulfill the promise of advances in data analysis by creating tools and methods to use advanced data analysis techniques and new technology to accelerate the collection of clinical data, remove barriers to patient access and monitor product safety, quality and effectiveness.

Health Economics & Patient Access – Create predictability and transparency of evidentiary requirements for coverage and improve pathways for coverage, coding and payment to speed patient access and amplify the patient voice in selection of treatment options

National Evaluation System for Health Technology Coordinating Center (NESTcc) – Work with stakeholders across the medical device ecosystem to catalyze the timely, reliable, and cost-effective development of Real-World Evidence to enhance regulatory and clinical decision-making.

MDIC Collaborators



Annual Public Forum

Every year, MDIC's Annual Public Forum (APF) brings together industry leaders from the medical device and diagnostics community to share insights on current trends in regulatory science.

To Join Us

To join MDIC, please contact us for an application and to confirm eligibility.

www.mdic.org
202-828-1600
info@mdic.org
@MDIConline

About MDIC Membership

Benefits of Membership

Being a member of MDIC connects you to network of medtech industry leaders working together to advance the future of public health.

MDIC provides its members with an active seat at the table to provide guidance and leadership through collaboration on regulatory, scientific, and patient value challenges within the medical device and diagnostic industry.

Our members shape the future of healthcare by providing subject matter expertise to working groups aimed at advancing approaches that promote patient access to innovative medical technologies.

The leadership and involvement of individuals and organizations from the public, private, and academic sectors are needed to make the benefits of MDIC's effort a reality.

Benefits Include:

- A process for identifying, documenting, prioritizing, and removing issues affecting benefits to patients
- Processes, support staff, and pooled project funding to enable efficient regulatory science research in areas of strategic importance to medical device stakeholders
- Educational forums in which to learn about the evolving regulatory science process new tools, standards, and test methods
- Searchable databases and links to relevant reports and methods
- Regular updates on the status of MDIC's activities and opportunities for involvement

Membership

Our members are leaders in the medical technology industry. MDIC currently offers membership to companies and organizations in the following categories:

- Medical Device
- Diagnostics
- HealthIT
- Digital Health
- Academic Institutions
- Healthcare Systems
- Payers
- Non-profit
- Patient Advocacy Groups

To Join Us

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MDIC Programs & Projects

Clinical Science

- Early Feasibility Studies
- Science of Patient Input

Digital Health & Technology

- Digital Health (Software)
- Cybersecurity
- Medical Extended Reality, Augmented Reality, and Virtual Reality
- Computational Modeling & Simulation
- 5G-Enabled Health Technologies
- Pathology Innovation Collaborative Community (PIcc)

Health Economics & Patient Value

- Patient Perspective Research
- Real-World Evidence

Advanced Manufacturing

- Clearing House
- Computer Software Assurance

NESTcc

- Pre-Market and Evidence Generation
- Systemic Harmonization and Interoperability Enhancement for Lab Data (SHIELD)

Case for Quality Collaborative Community

- Voluntary Improvement Program (VIP)
- Medical Device Information Analysis & Sharing (MDIAS)
- Making CAPA Cool
- Leadership Engagement
- Accelerate Sustainable Capability (ASC) Clinical Diagnostics
- Somatic Reference Samples (SRS) Initiative
- Artificial Intelligence and Machine Learning for In Vitro Diagnostics (AI/ML)
- Open Hand (previously COVID Real-World Evidence Project)

Medical Device Cybersecurity

Rapidly evolving technology has revolutionized the quality of healthcare with interconnected devices one of the leading advancements. The connectivity these devices provide, although beneficial in capturing data, can increase cybersecurity risks. To protect patients from these risks, the medical device ecosystem has a shared responsibility to ensure the security of devices, diagnostics, healthcare services, and platforms. Those in this shared area of risk are working collaboratively to comprehensively address cybersecurity vulnerabilities and threats. Recent medical device regulatory guidance from the U.S. Food and Drug Administration and its global counterparts confirms the need to tackle cybersecurity concerns with multi-pronged approaches. MDIC's cybersecurity program, through multiple, collaborative initiatives, focuses on pre-market and post-market strategies relevant to medical device and diagnostics cybersecurity risk management.

MDIC Cybersecurity Projects

- MedTech Cybersecurity Maturity Benchmarking
- Penetration Testing for Medical Devices
- Risk Management Methodologies Across the Total Product Lifecycle
- Threat Modeling
- Coordinated Vulnerability Disclosure

Medical Device Cybersecurity Resources from MDIC

- Playbook for Threat Modeling Medical Devices
- Advancing Coordinated Vulnerability Disclosure (CVD): MDIC Medical Device Cybersecurity Report
- MDIC Medical Device Cybersecurity Maturity: Industry Benchmarking Report and Tool
- Training Program: Medical Device Threat Modeling Bootcamps

MDIC member organizations have multiple opportunities to engage in various cybersecurity working groups or projects. These projects are governed by the MDIC Cybersecurity Steering Committee, which comprises global thought leaders from the industry as well as regulatory bodies like US FDA.

Contact us at cybersecurity@mdic.org or reach out to MDIC cybersecurity program staff

- Jithesh Veetil | Senior Program Director, jveetil@mdic.org
- Noor Falah | Project Manager, nfalah@mdic.org

Somatic Reference Samples (SRS) Initiative

The Somatic Reference Samples (SRS) Initiative is a public-private partnership convened by the Medical Device Innovation Consortium (MDIC) guiding the development of reference samples that can be used to develop and validate Next Generation Sequencing-based cancer diagnostics and support regulatory submissions. Ensuring that oncology patients receive accurate results is imperative. However, lack of agreed upon, well-characterized, community validated, and data benchmarked reference samples create potential challenges for efficient development of cancer diagnostic tests. Without proven reference samples, there is potential for misinterpreting results.

This initiative is a pilot project, fully funded by industry and philanthropic organizations, to develop, manufacture, and make available an initial set of ten reference samples. The samples will be engineered to contain ten cancer variants and will include validated data sets.

Over and above development and regulatory application, these reference samples and the diagnostic testing they will support, have the potential to improve reimbursement decisions, adoption, and disease management.

SRS Initiative Steering Committee include FDA, NIH, NIST, CDC, diagnostics manufacturers, funding organizations and payors.

Initiative Goals

- Create a pathway for improved validation and accuracy of next-generation sequencing-based diagnostic tests using authoritatively characterized and validated somatic reference samples for diagnostics.
- Seek to transform the regulatory review process, possibly obviate steps expediting companion diagnostics and therapeutic development.
- Build a sustainable model for somatic reference samples and dataset generation.
- Expand reference sample generation to include other cancer variants/other diseases.

Learn More About MDIC'S SRS Initiative

MDIC Website – SRS Initiative

www.mdic.org/project/cancer-genomic-somaticreference-samples/

SRS Landscape Analysis Report

www.mdic.org/resource/srs-landscape-analysisreport/

YouTube Video: MDIC Live with Maryellen de Mars

www.youtube.com/watch?v=zz5YOfFJpu4

FDA Website

www.fda.gov/medical-devices/in-vitro-diagnostics/precision-medicine

Contact

Contact us at diagnostics@mdic.org or reach out the MDIC SRS program staff:

- Maryellen de Mars | Program Director, mdemars@mdic.org
- Pipper White | Program Manager, pwhite@mdic.org

Artificial Intelligence and Machine Learning for in Vitro Diagnostics

As technology advances, software incorporating artificial intelligence (AI) and machine learning (ML) has become a critical component of medical devices including in vitro diagnostics (IVDs). Currently, there is no suitable regulatory framework for addressing post-launch improvements of artificial intelligence machine learning-enabled medical devices while ensuring their safety and effectiveness for their intended use.

The project was established in pursuit of a consensus for how to perform and evaluate iterative improvements. The FDA document "Proposed Regulatory Framework for Modification to Artificial Intelligence/Machine Learning-Based Software as a Medical Device–Discussion Paper and Request for Feedback" from 2019 discussed the concept of a plan for change control in devices of this nature. In addition to evaluating the use of real-world data, the output will evaluate appropriate metrics used to address the changing applications including software in a medical device (SiMD) and software as a medical device (SaMD).

Initiative Goals

- Develop a predetermined change control plan for AI/ML-enabled IVDs including both Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) that leverages the use of Real-World Data.
- Address iterative improvements that can occur post-launch for AI/MLenabled medical devices, including in vitro diagnostics, while ensuring their safety and effectiveness for their intended use.
- Produce tools and resources to establish common terminology across the sector and to include a software pre-specifications (SPS) template and an algorithm change protocol (ACP) template.

Learn More

MDIC Website – AI/ML for In Vitro Diagnostics

www.mdic.org/program/aiml/

FDA Documents:

- Artificial Intelligence and Machine Learning (AI/ML) Enabled Medical Devices
  www.fda.gov/medical-devices/software-medicaldevice-samd/artificial-intelligence-and-machinelearning-aiml-enabled-medical-devices
- Proposed Regulatory Framework for Modification to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) – Discussion Paper and Request for Feedback
  www.fda.gov/medical-devices/software-medicaldevice-samd/artificial-intelligence-and-machinelearning-software-medical-device

In Vitro Diagnostics Real World Evidence Open Hand (COVID Real World Evidence)

Regulatory submission interactions are typically confidential. With the lens of a public health emergency, Open Hand used this opportunity to build a framework for utilizing real-world data and real-world evidence to support regulatory submissions and decision-making. In this collaborative pilot effort, medical device manufacturers shared high-level learnings to support the transition of SARS-CoV-2 diagnostic test that had Emergency Use Authorization to full market authorization with support from an interactive regulatory review supplied by the US Food and Drug Administration.

Initiative Goals

- Provide a transparent process to evaluate new technology and methods.
- Capture the 'how' to share with the broader community while staying in the precompetitive space and protecting proprietary technology and methods
- Disseminate recommendations from this important exercise in the form of an instructional whitepaper and an article in a peer-reviewed journal.

Learn More

MDIC Website – Open Hand

www.mdic.org/project/covid-rwe/

MDIC Framework: Real-World Clinical Evidence Generation: Advancing Regulatory Science and Patient Access for In Vitro Diagnostics (IVDs)

www.mdic.org/resource/ivd-rwe-framework/

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

www.fda.gov/regulatory-information/search-fda-guidance-documents/usereal-world-evidence-support-regulatory-decision-making-medical-devices

MDIC's Clinical Diagnostics Initiative

The IVD Initiative falls under MDIC's Clinical Diagnostics Initiative. MDIC's Clinical Diagnostics Initiative addresses the biggest barriers to collecting adequate clinical evidence in support of new medical technology. Clinical Diagnostics stakeholders work together to create blueprints for innovative clinical trials techniques, develop standards and metrics for effective clinical trial designs, and encourage the collection of adequate and appropriate clinical and patient preference data.

Computational Modeling and Simulation

Widely used in the physical sciences, Computer Modeling and Simulation (CM&S) is the use of physical or logical representation of a given system or model to generate data. This data is then used to make predictions. In regulatory science, these have been used with a variety of outcomes in the regulatory process. MDIC's Computer Modeling and Simulation program spotlight these strategies to balance the desire for certainty in device performance while limiting the delay associated with finding patients that fit restrictive criteria while increasing certainty for use in the regulatory process as valid scientific evidence.

Current CM&S Projects

- Blood Damage Modeling
  - Hemolysis Working Group
  - Thrombosis Working Group
- CM&S Landscape Survey
- Publicly Funded Human Body Simulation models
- Virtual Patient Project
- ENRICHMENT trial (in silico clinical trial) Project & Industry Advisory Council (IAC)
- External Evidence Methods (EEM)

MDIC Landscape Report on Medical Device Computational Modeling and Simulation

This MDIC Landscape Report on Computational Modeling and Simulation presents results from MDIC's most recent CM&S Survey, which addressed a diverse range of stakeholders. This report will discuss the potential of CM&S to reduce product development costs, speed time to market, and better serve patients with safe and effective medical devices. Case studies included in this report will demonstrate tangible evidence of the value of simulation and modeling to both industry and regulators. The report will also address current barriers to more widespread adoption and offers recommendations for future actions.

Learn More

Learn more about MDIC and CM&S projects by visiting
www.mdic.org/program/computational-modelingand-simulation-cms/

MDIC member organizations have multiple opportunities in various CM&S projects. These projects are governed by the MDIC CM&S Steering Committee which comprises of global thought leaders on medical device Computational Modeling Simulation from across industry and the private sector.

Early Feasibility Studies

In 2013, Early Feasibility Studies were becoming increasing difficult to complete in the United States. With lengthy approval processes for the Investigational Device Exemption and Institutional Review Board, many organizations were going overseas to complete these studies. In-country early feasibility studies can facilitate direct and interactive collaboration between FDA, sponsors, and innovators in early product lifecycle stages.

Medical Device Innovation Consortium's Early Feasibility Studies program has been diligently working toward making innovation more accessible in the United States by producing study toolkits, budgeting templates, and legal templates addressing site contracting and informed consent. Identifying other means to make these studies more accessible, program volunteer leadership identified nuanced needs in the area of electrophysiology and neurovascular, which are a focus of current working groups.

MDIC's Clinical Science Initiative

The Early Feasibility Studies Program falls under MDIC's Clinical Science Initiative. MDIC's Clinical Science Initiative addresses the biggest barriers to collecting adequate clinical evidence in support of new medical technology. Clinical Science stakeholders work together to create blueprints for innovative clinical trials techniques, develop standards and metrics for effective clinical trial designs, and encourage the collection of adequate and appropriate clinical and patient preference data.

Resources

- Blueprint for Early Feasibility Study Success is a best practices roadmap for navigating complexities.
- FDA Guidance on Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

If you are interested in learning more, please contact MDIC today.

Learn More About MDIC's Early Feasibility Studies Program

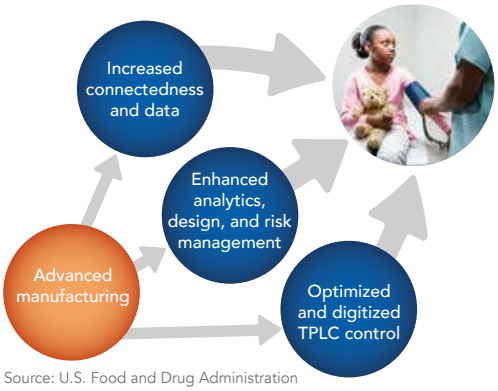
Learn more about MDIC's Early Feasibility Studies by visiting www.mdic.org.

Advance Manufacturing Clearing House

Advanced Manufacturing in medical devices is an approach that uses innovative techniques that applies the use of electronic information, computer technology, machinery, materials, and tech-enabled management to improve the quality and process of production. Each organization has unique needs and starting points in the journey toward an advanced manufacturing process.

Why Advanced Manufacturing?

- Ensure safe, effective and compliant output
- Improve product quality and yield
- Maintain and improve process controls
- Increase operational effectiveness
- Reduce unplanned downtime
- Enable educated decisions
- Increase product intelligence
- Improve after-market support

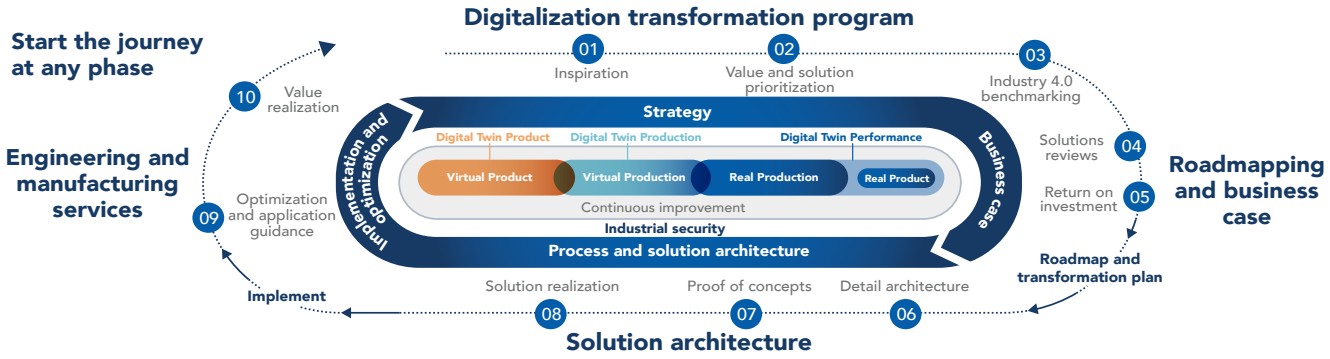


Source: U.S. Food and Drug Administration

Medical Device Innovation Consortium with the FDA will be piloting an Advanced Manufacturing Clearing House program with the goal of contributing expertise and capital to implement advanced manufacturing technologies into the production process for device manufacturers. Objectives include improving design, supply, production, distribution, tracking, device reliability, overall quality, and safety across the product life cycle. Examples of technologies include additive and generative part design, digital twins, and digital threads (e.g., modeling and simulation for virtual design verification, validation and design transfer), and data-driven closed-loop quality.

Learn More About the Advanced Manufacturing Clearing House Team

For further information contact the MDIC Case for Quality Team at AMCH@mdic.org.

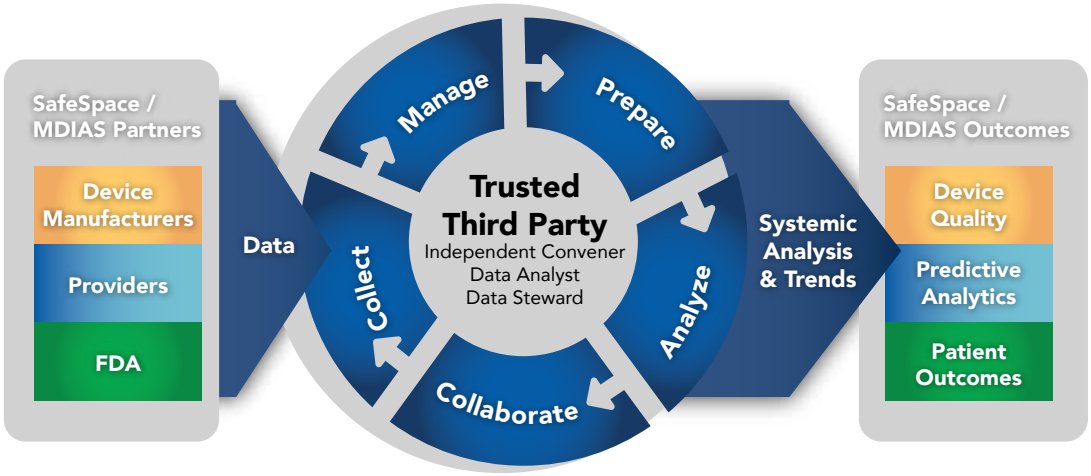


Case for Quality

Safe Space / Medical Device Information Analysis & Sharing (MDIAS)

During the medical device development process and in real-world environments, an abundance of data is collected. Currently siloed within medical device companies for exclusive organizational use and for patient privacy, these data sets vary in quality and format. Developing a manner to collect and analyze data would help identify trends in device quality and safety to provide powerful insights for improving outcomes while safeguarding data.

The Safe Space/ MDIAS initiative focuses on a data-sharing collaborations to analyze and share medical device data from various public and non-public sources to improve healthcare outcomes. Data is safeguarded by an independent trusted third party to foster broad participation and engagement.



How To Get Involved

Learn more and share your ideas!

Get to know Safe Space / MDIAS! If you have an idea for this project, we want to hear from you. For further information contact the MDIC Case for Quality Team at CfQcc@mdic.org.

Case for Quality Collaborative Community (CfQcc)

The Safe Space / MDIAS Initiative is an effort of the Case for Quality Collaborative Community and offers a unique forum for medical device stakeholders to move beyond baseline regulatory compliance activities and collaboratively develop sustained predictive practices. These predictive practices could advance medical device quality and safety to achieve better patient outcomes. Collaborative Communities provide a forum for public and private sector members to proactively work together to achieve common objectives and outcomes.

Culture of Quality

An Initiative of the Case for Quality Collaborative Community

In an industry facing increasing competition, regulations, customer demands, and unprecedented innovation, a culture of quality cultivated by leaders and executives, serves as a clear competitive differentiator. The responsibility of quality in an organization encompasses everyone. Continuous commitment to quality and excellence transcends compliance, from design to patient outcomes, and can only be manifested in an organizational culture of quality. MDIC has taken an opportunity to develop tools and resources that provide concrete goals and actions that help leaders move from a reactive to a proactive approach, to quality.

In a study from the Medical Device Innovation Consortium, 90% of respondents reported leaders actively promoting quality in activities and functions. 63% prioritized high-quality performance over costs and competing priorities. Most organizations proactively encouraged understanding of how quality applies to jobs and performance reviews.

To learn more visit: www.mdic.tech/CultureOfQualitySurvey

Gathering best practice for leaders, MDIC facilitated the creation of the Quality Leadership Engagement Playbook. The playbook describes 10 best practices that guides leaders navigating the change from a culture of compliance to a culture of quality.

Learn More About MDIC's Culture of Quality Initiative

Learn more about MDIC's Culture of Quality Initiative by visiting www.mdic.org.

FDA does not lead Collaborative Communities, and their work does not replace established regulatory mechanisms. However, FDA may choose to participate in a Collaborative Community and support, leverage, and/or adopt solutions that emerge.

Breakout Sessions

Overview

Introduction of all Participants (each table)

- Name, title, organization – two minutes total

We have identified Breakout Topic Leads

- Deliver 1-slide summary in plenary session (feel free to change if ok)

Rules of Engagement

- Every member in the group should contribute
- Share your experience and perspective
- Respect the opinions of others
- Maintain confidentiality and respect antitrust requirements
- Focus on the topic at hand and try not to move on to tangential issues
- Use parking lot for important topics for subsequent discussion

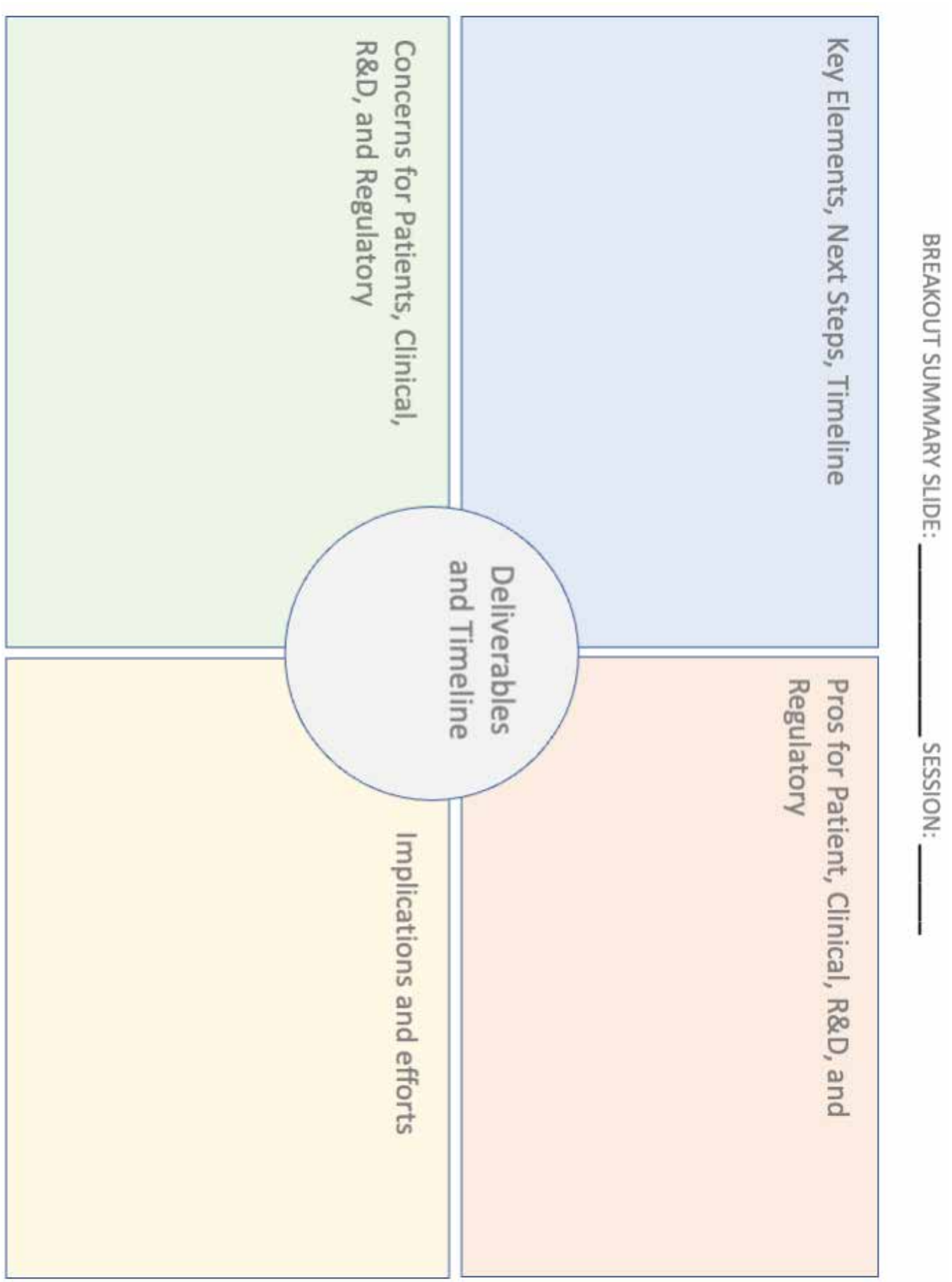
Last Five Minutes

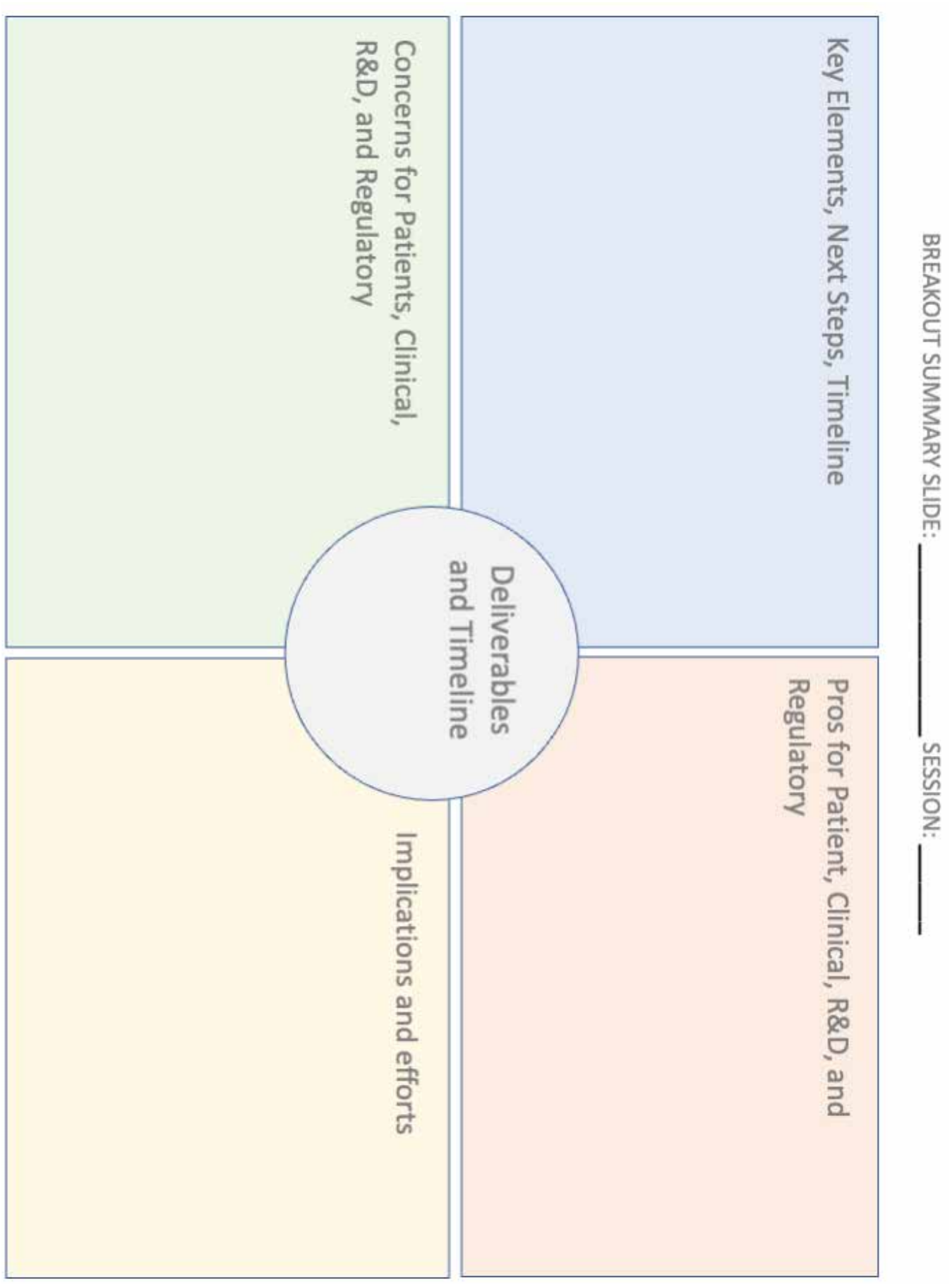
- Confirm champion is prepared
- Check 1-slide summary for consolidation and projection in plenary session

Format

Overview – "Name of the group"

- What is missing to move "XXX" forward
- 3 key elements that the group considered most meaningful next steps including timelines
- What is the goal of this project and timeline?
- "How will these elements be valuable from a clinical, regulatory, and R&D perspective?"
- What is the clinical impact and/or relevance to the patient?
- What are possible concerns/risks to the patient?
- Explain the regulatory implications and advantages of pursuing this project in relation to digital pathology.


BREAKOUT SUMMARY SLIDE: _____ SESSION: _____
Key Elements, Next Steps, Timeline
Pros for Patient, Clinical, R&D, and Regulatory
Deliverables and Timeline
Concerns for Patients, Clinical, R&D, and Regulatory
Implications and efforts


BREAKOUT SUMMARY SLIDE: _____ SESSION: _____
Key Elements, Next Steps, Timeline
Concerns for Patients, Clinical, R&D, and Regulatory
Deliverables and Timeline
Pros for Patient, Clinical, R&D, and Regulatory
Implications and efforts

BREAKOUT SUMMARY SLIDE: _____ SESSION: _____

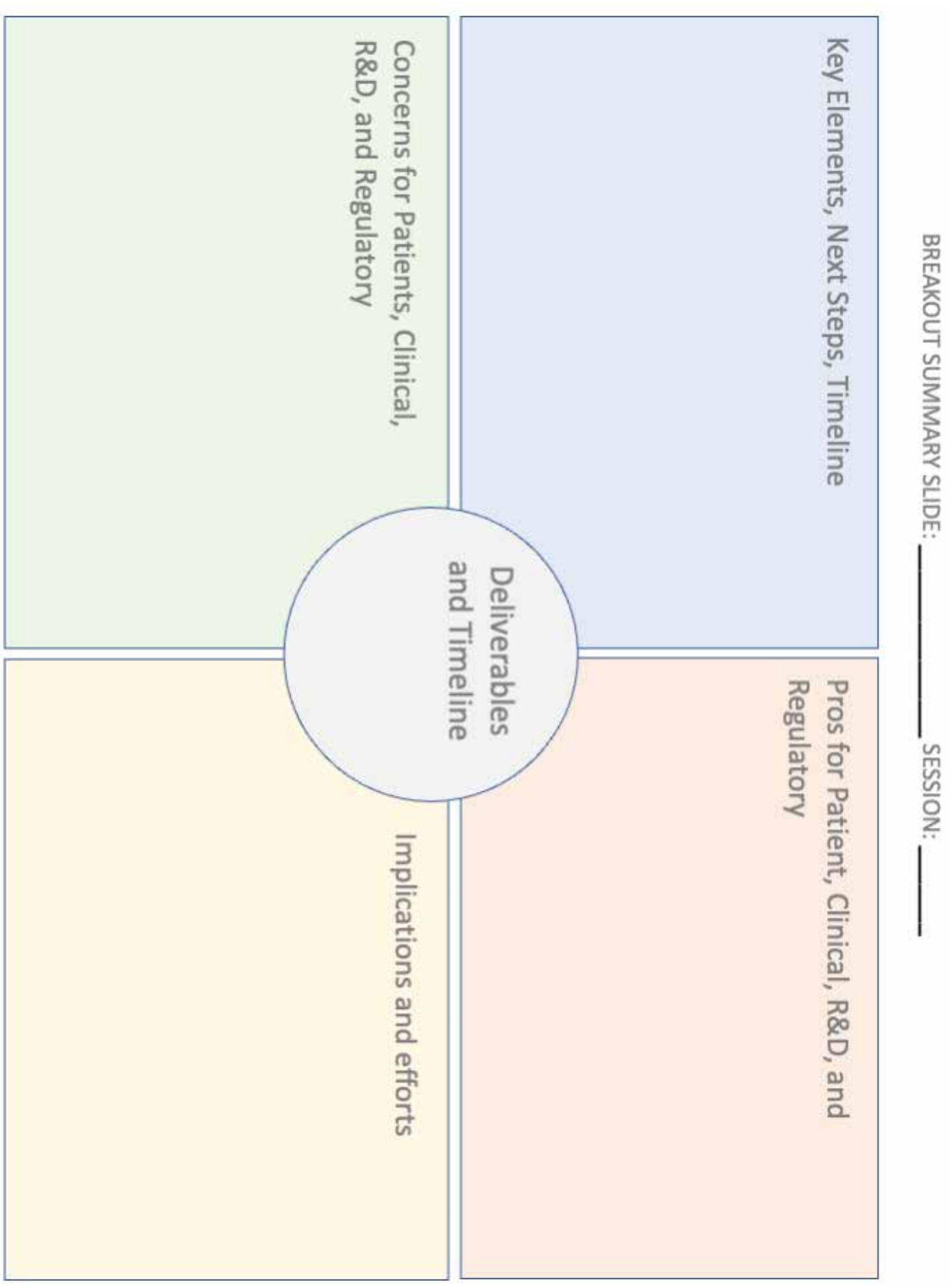
Key Elements, Next Steps, Timeline

Pros for Patient, Clinical, R&D, and Regulatory

Concerns for Patients, Clinical, R&D, and Regulatory

Implications and efforts

Deliverables and Timeline


BREAKOUT SUMMARY SLIDE: _____ SESSION: _____
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Appendix

What is Regulatory Science?

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.https://www.fda.gov/science-research/science-and-research-special-topics/advancing-regulatory-science

Exploratory science: development of new technologies and novel methodologies targeting unmet needs in medicine

- Example: An analysis of 2,148 patients from 9 drug trials found that stromal tumor-infiltrating lymphocytes had a strong prognostic role in early-stage TNBC[1].
  - Focus is on the clinical role of the biomarker.

Regulatory science: development and standardization of tools and methods that generalize across biomarkers, devices, and diseases

- Example: Modeling and simulation have demonstrated that a split-plot study design can permit smaller diagnostic imaging studies with a nominal loss in statistical precision[2].
- Focus is on the split-plot method that can be used in many studies.
- Example: Imaging phantoms and systems can be modeled and simulated that approximate the materials and behavior of anatomy as "seen" by an imaging device[3].
  - Focus is on using the phantom to assess the performance characteristics of an imaging device in a reproducible way.
- Example: A dataset of images with (reference standard) annotations that demonstrably represents a clinical population that can be used to test artificial intelligence models[4].
  - Focus is on the importance of dataset characterization, importance of training pathologists providing annotations, and appropriate methods to assess performance.

More Information

Accelerating Medical Device Innovation with Regulatory Science Tools

https://www.fda.gov/news-events/fda-voices/accelerating-medical-device-innovation-regulatory-science-tools

https://cdrhhome.fda.gov/spaces/1/cdrh-news/articles/feature/4158/regulatory-science-tools-to-accelerate-medical-device-innovation

Medical Device Development Tools (MDDT)

https://www.fda.gov/medical-devices/medical-device-development-tools-mddt

Catalog of Regulatory Science Tools

https://www.fda.gov/medical-devices/science-and-research-medical-devices/catalog-regulatory-science-tools-help-assess-new-medical-devices

1 S. Loi et al., "Tumor-Infiltrating Lymphocytes and Prognosis: A Pooled Individual Patient Analysis of Early-Stage Triple-Negative Breast Cancers," J. Clin. Oncol., vol. 37, no. 7, pp. 559–569, Mar. 2019, doi: 10.1200/JCO.18.01010.

2 W. Chen, Q. Gong, and B. D. Gallas, "Paired split-plot designs of multireader multicase studies," Journal of Medical Imaging, vol. 5, p. 031410, 2018, doi: 10.1117/1.JMI.5.3.031410.

3 A. Badano et al., "Evaluation of digital breast tomosynthesis as replacement of full-field digital mammography using an in silico imaging trial," JAMA Network Open, vol. 1, no. 7, pp. e185474-, 2018, doi: 10.1001/jamanetworkopen.2018.5474.

4 S. Dudgeon et al., "A pathologist-annotated dataset for validating artificial intelligence: A project description and pilot study," J Pathol Inform, vol. 12, no. 1, p. 45, 2021, doi: 10.4103/jpi.jpi_83_20.

Notes