Michael J. Halaiko, CIPP/E

Shareholder
Baltimore | 410.862.1073 | mhalaiko@bakerdonelson.com
Washington, D.C. | 202.508.3400

Mr. Halaiko (Mike) is a shareholder in Baker Donelson's Baltimore and Washington, D.C. offices and a member of the Health Law Group and Data Protection, Privacy and Cybersecurity Team.

Mike is a nationally recognized attorney, strategist, and thought leader at the intersection of life sciences, clinical research, AI governance, and global data privacy compliance. He counsels pharmaceutical companies, biotech innovators, contract research organizations (CROs) and site management organizations (SMOs), health systems, and AI-driven technology companies on high-stakes regulatory, contracting, and operational risk challenges. His work routinely spans the United States, the UK, and the EEA – bringing regulatory precision, commercial pragmatism, and AI fluency to mission-critical initiatives.

A Certified Information Privacy Professional (CIPP/E) and AI governance trained, Mike leads on General Data Protection Regulation (GDPR), UK GDPR, CTIS compliance, cross-border data transfers, AI model governance, and privacy-preserving AI deployment in research and commercial environments. He designs scalable compliance infrastructures, negotiates complex global agreements, and operationalizes data protection programs that withstand regulatory scrutiny and accelerate innovation.

Known for transforming complexity into execution, Mike serves as outside general counsel to life sciences companies, delivering strategic guidance on AI risk management, clinical trial contracting, regulatory pathways, privacy engineering, data governance, risk allocation, and litigation readiness. He is widely recognized for his ability to align legal strategy with business imperatives in fast-maturing and highly regulated technology markets.

Mike leads Baker Donelson's Life Science and Health Tech working group; serves on the Maryland Tech Council Board of Directors; and formerly chaired a national law firm's Pre-Clinical and Clinical Study Practice Group. His thought leadership has been featured by *Law360*, *Bloomberg Law*, *The American Lawyer*, *Baltimore Business Journal*, *The Baltimore Sun*, *The Daily Record*, *Corporate Compliance Insights*, *OneTrust, Medical Device & Diagnostic Industry*, *Life Science Leader*, and more. He is a frequent national speaker on AI regulatory frameworks, clinical research compliance, GDPR, clinical trial contracting, and data-driven health innovation.

Representative Matters

- Developed master clinical trial agreement (mCTA) templates for pharmaceutical companies initiating global clinical development, supporting studies across the U.S., EU, APAC, and Latin America, with a focus on regulatory compliance, data protection, IP ownership, and risk allocation.
- Created clinical trial contracting "playbooks" for pharmaceutical sponsors to streamline site negotiations, including pre-approved alternative language and a negotiation matrix for key mCTA provisions. Empowered CROs and in-house contracting teams to resolve routine issues independently, reducing legal escalations, and accelerating site activation timelines.
- Served as embedded external in-house legal support for a major pharmaceutical sponsor, overseeing global Phase III clinical trial agreements, data privacy compliance (including cross-border data transfers), and operational legal support across multiregional study programs.

- Advised a Europe-based global pharmaceutical company on GDPR applicability to U.S.-only clinical trials involving exclusively non-EU participants, clarifying that GDPR obligations remained triggered due to the company's EU establishment. Provided guidance on data minimization, regulatory distinctions between U.S. de-identified data and GDPR anonymized data, and required privacy documentation to support ongoing compliance.
- Advised a U.S.-based pharmaceutical company conducting clinical trials in the EU regarding the appropriate data protection role allocation between the sponsor, European clinical trial sites, and CROs. Conducted a detailed analysis of GDPR's definitions regarding independent controllership versus joint controllership versus controller-processor relationships, ensuring the company appropriately structured its data protection agreements, responsibilities, and liability allocations.
- Assisted pharmaceutical sponsor in structuring GDPR-aligned data processing agreements for EU clinical sites and CROs, operationalizing cross-border transfer compliance under Chapter V. Implemented SCCs and advised on supplementary technical and organizational measures supporting transfers to non-adequate jurisdictions, including the U.S.
- Represented a U.S. pharmaceutical company in drafting and negotiating a strategic clinical collaboration agreement to enable combinational testing of its investigational product with an FDA-approved therapy, including oversight of intellectual property rights, regulatory considerations, data ownership, safety reporting, confidentiality, and commercialization pathways.
- Directed the externally sponsored research contracting function for international pharmaceutical sponsor, designing global agreement templates and leading site negotiations to enable consistent, compliant, and efficient deployment of research initiatives across multinational study networks.
- Advised a global clinical research organization in connection with a major pharmacy chain's attempted termination of a data supply agreement. Provided strategic counsel on contractual rights, intra-company data sharing, regulatory risk, and financial exposure, and supported negotiations that resulted in the renewal of a seven-figure agreement.
- Advised a leading life sciences company in negotiating a $100 million multiyear CDMO manufacturing agreement for the commercial-scale production of its cell therapy product, addressing technology transfer, quality, supply assurance, and commercialization requirements.
- Represented an AI-driven clinical trial enrollment technology company in structuring its commercial contracting framework, drafting standardized customer agreements, and establishing IP protection, data rights, and U.S. regulatory compliance guardrails for deployment within the clinical research ecosystem.
- Modernized contracting operations for a global CRO/SMO by developing standard templates and streamlined negotiation processes to drive efficiency, consistency, and scalable growth across international clinical programs.
- Advised a startup CRO in building a scalable contracting framework, including drafting master services agreements (MSAs) for sponsor engagements and standardized clinical trial agreement (CTA) templates for site contracting.
- Partnered with a U.S. university to build and operationalize a GDPR compliance program for EEA-based research, establishing data protection roles, transfer mechanisms, consent and privacy documentation, and implementation protocols to support compliant multinational study activities.

Professional Honors & Activities

- Listed in *The Best Lawyers in America*® in the areas of Commercial Litigation (2023 – 2026); Mass Tort Litigation/Class Actions – Defendants (2023 – 2026); Medical Malpractice Law - Defendants (2024 – 2026); Personal Injury Litigation - Defendants (2025, 2026); Product Liability Litigation – Defendants (2020 – 2026)
- Named among *The Daily Record*'s Leaders in Law: Leadership in Law (2025)
- Listed in *Maryland Super Lawyers* for Personal Injury Defense: Products (2021)
- AV® Preeminent™ Peer Review Rated by Martindale-Hubbell

- SmartCEO's Centers of Influence Award (2016)
- Listed in Maryland Rising Stars by Super Lawyers for Construction Litigation and Personal Injury Defense: General (2011 – 2012); Personal Injury Defense: Products (2013 – 2014)
- Member – American Bar Association
- Member – Baltimore City Bar Association
- Member – Maryland Bar Association
- Member – Maryland Chamber of Commerce's Healthcare & Biopharma Policy Committee
- Member – Sports and Fitness Industry Association, Legal Task Force
- Member – International Association of Privacy Professionals
- Member – Maryland Tech Council Board of Directors
- Gorilla Doctors
  - Board President (2018 – 2022)
  - Board Vice President (2023 – present)
  - Board Member (2023 – present)
- KIND (Kids in Need of Defense) Pro Bono Attorney (2019 – present)
- Maryland Volunteer Legal Services Pro Bono Lawyer (2003 – present)

Publications

- "Goals For and Challenges to the Push for More Clinical Trials in the EU" (December 2025)
- "Maryland's New Online Data Privacy Act: Sweeping Protections for Consumer Health Data and Implications for Health Care, Life Sciences, and AI," republished November 10, 2025, by *The Legal Intelligencer* (October 2025)
- "Immediate Action Items to Prepare for Website Automatic Opt-Out Signal Mandates," republished in *Law360* (October 2025)
- "President Trump and White House Announce New Overseas Pharmaceutical Tariff" (October 2025)
- "How Businesses Can Prepare for Maryland's New Data Privacy Law," *Baltimore Business Journal* (October 2025)
- "Practical Next Steps for Businesses as Maryland's Updated Consumer Data Privacy Laws Take Effect in October " (September 2025)
- "DOJ Bulk Data Rule: Key Takeaways for Healthcare and Life Sciences" (May 2025)
- "Executive Orders on Domestic Production of Critical Medicines and Biological Research Security" (May 2025)
- "DOJ Issues Additional Guidance and Clarification on the Bulk Data Transfer Rule: What U.S. Businesses Need to Know ," republished May 5, 2025, in *Corporate Compliance Insights* (April 2025)
- "OCR Issues "Dear Colleagues" Letter Regarding AI in Medicine," republished January 27, 2025, in *The American Lawyer* (January 2025)
- "Texas Court Issues Injunction on 2024 HIPAA Reproductive Privacy Rule" (December 2024)
- Co-author – "AI Use Cases in Clinical Research," *Bloomberg Law* (November 2024)
- Co-author – "Maryland: The Online Data Privacy Act of 2024 Gains Traction – What Businesses Need To Know Regarding The Proposed Legislation," *OneTrust Data Guidance* (April 2024)
- Co-author – "AI: Considering the Regulatory and Legal Implications," *Medical Device & Diagnostic Industry* (November 2023)
- Co-author – "Considerations For Compliance With CTIS Submissions Under The EU-CTR," *Life Science Leader* (May 2023)
- Co-author – "The Anatomy of a Clinical Trial Agreement," *Compliance Today* (February 2023)

Speaking Engagements

- "AI Implementation in Clinical Research: Risks, Benefits and Compliance Considerations," Maryland Tech Council Bio Innovation Conference (September 2025)

- Host – "Data Governance and Privacy Compliance," Roundtable, Sixth Annual Maryland Tech Council Technology Transformation Conference (February 2025)
- "Artificial Intelligence: A Brave New World," Mid Atlantic Society of Healthcare Risk Management AI Seminar (December 2024)
- "AI Governance and Risk Management: Legal Considerations in the Development and Deployment of Generative AI," Perrin Conferences (April 2024)

Education

- Ohio State University Moritz College of Law, J.D., 1999
- Capital University, B.A., 1996, magna cum laude

Admissions

- District of Columbia, 2000
- Maryland, 2000
- Pennsylvania, 2011
- West Virginia, 1999
- Supreme Court of the United States
- U.S. Court of Appeals for the Fourth Circuit
- U.S. District Court for the District of Columbia, the District of Maryland, the Eastern District of Pennsylvania, and the Northern and Southern Districts of West Virginia