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All the Buzz:

The Latest Developments for Emerging & Tech Companies

Regulatory Developments in the Life Sciences Sector and How it Impacts Life Sciences Companies

November 7, 2023

Changes to the Regulatory Landscape for Clinical Trials

FDA Guidance Seeks to Modernize Clinical Trials

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- Clinical trial design and implementation provide the backbone of a strong submission to FDA for drug and biologic products, as well as many medical device products
- A confluence of factors has increased agency guidance and scrutiny
  - Ongoing impact of COVID
  - Diversity, equity and inclusion
  - Congressional interest
  - Patient groups and advocates
  - Real World Evidence (RWE)
- Sponsors certainly want to ensure compliance with evolving guidance, but also should seek to identify opportunities for innovation and efficiency

Ensuring Diversity in Clinical Trials

Diversity in Clinical Trials

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- There are public policy rationale as well as scientific ones
- Important: diversity refers not only to demographic characteristics…
  - *e.g.*, race/ethnicity, age, sex

  but also to non-demographic characteristics
  - *e.g.*, patients at an extreme of a weight range, patients with comorbid conditions, and patients with disabilities
- Recent guidance addressing Race and Ethnicity Diversity Plans
  - *Draft Guidance, Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry* (April 2022)
    - Public outreach and education
    - Clinical trial site selection
    - Language
    - Technology

Conducting Clinical Trials Remotely

Remote and Decentralized Clinical Trials (DCTs)

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- A positive impact of the challenges of COVID
  - Also bolsters efforts to increase diversity
- *Draft Guidance, Decentralized Clinical Trials for Drugs, Biological Products, and Devices* (May 2023)
  - Alternate locations, including participant's home, a local health care facility, or a nearby laboratory
  - Use of digital health technologies (DHTs)
- Important considerations
  - Physical location for inspection purposes/record-keeping
  - Non-inferiority trials: when the effect size of an active control drug has only been determined in a traditional site-based clinical trial
  - Telehealth vs. In-person visits
  - Evaluation and management of adverse events

Additional Challenges for Rare Disease Clinical Trials

Rare Diseases Pose Additional Challenges

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- Smaller patient populations and potentially novel endpoints
- Sponsors should engage early in the drug development process with patient advocacy groups, experts, and FDA
- Consider re-enrolling participants from early-phase trials into later-phase randomized trials when studying the effectiveness of treatments for rare diseases.
  - Open-label extension study with broader inclusion criteria after their preceding studies to encourage participation and to allow study participants, including those who received a placebo, to have access to the investigational treatment

Ensuring Compliance and Data Integrity

Data Integrity and Compliance

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- Ensure high standards for compliance and data integrity in all clinical trial agreements
  - Record-keeping
  - Auditing
- Considerations for DHTs: validation and verification
- Remote trials: continuous oversight of data integration, flow, and quality
- Additional factors for controlled substances

How Clinical Trials affect Representations and Warranties in M&A and Investment Deals

NVCA—New!—We Have The Team and Processes:

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- (c) To the extent the Company **maintains** or transmits **protected health information**, as defined under 45 C.F.R. § 160.103, as a covered entity or business associate, as defined therein, (i) the Company is in compliance with the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), as amended by the Health Information Technology for Economic and Clinical Health Act, including all binding rules and regulations promulgated thereunder and (ii) without limiting the generality of the foregoing, the Company: (A) has designated **a privacy official and a security official** who is responsible for the development and implementation of the entity's privacy and security compliance infrastructure; (B) has entered into, and complies with the terms of, business associate agreements as described under HIPAA when required by HIPAA; (C) has provided regular training to its workforce with respect to and to the extent required for compliance with HIPAA; (D) **has adopted, and has been in compliance with, privacy and security compliance policies and procedures in compliance with HIPAA**; and (E) has completed regular security risk analyses in compliance with HIPAA and has addressed and remediated all material threats, vulnerabilities and deficiencies that have been identified.

NVCA—New!—We Are In Compliance

Healthcare Laws. The Company is and has been in **material compliance** with all applicable Healthcare Laws. "Healthcare Laws" means all applicable **federal, state, or local health care laws**, each as amended, relating to the regulation of the Company, including but not limited to laws regarding fraud and abuse; kickbacks; self-referrals; fee-splitting; the operation of healthcare provider networks or risk bearing entities; beneficiary inducement, false claims, false billing, false coding, reimbursement, and reassignment; record retention; healthcare professional or entity licensure, qualifications, accreditations, or scope of practice requirements, including the practice of telehealth and healthcare professional supervision; the corporate practice of a learned or licensed healthcare profession; health information privacy laws, including those relating to mental health and substance abuse, including HIPAA; and all applicable implementing regulations, rules, ordinances, and orders related to any of the foregoing.

IPO Preparedness for Companies with Clinical Trials

NVCA—New!—We're cool with the FDA!

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2.31 Preclinical Development and Clinical Trials. The studies, tests, **preclinical development and clinical trials**, if any, conducted by or on behalf of the Company are **being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional and scientific standards** for products or product candidates comparable to those being developed by the Company and all applicable laws and regulations, including the **Federal Food, Drug, and Cosmetic Act** and 21 C.F.R. parts 50, 54, 56, 58, [312, and 812]. The descriptions of, protocols for, and data and other results of, the studies, tests, development and trials conducted by or on behalf of the Company that have been furnished or made available to the Purchasers are accurate and complete in all material respects. The Company has not received any notices or correspondence from the U.S. Food and Drug Administration ("FDA") or any other governmental entity or any institutional review board or comparable authority requiring the termination, suspension or material modification of any studies, tests, preclinical development or clinical trials conducted by or on behalf of the Company.]

NVCA—Bonus!
CFIUS—the cost of a turbulent world

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2.30 CFIUS Representations. The Company does not engage in (a) the design, fabrication, development, testing, production or manufacture of one or more "**critical technologies**" within the meaning of the Defense Production Act of 1950, as amended, including all implementing regulations thereof (the "DPA"); (b) the ownership, operation, maintenance, supply, manufacture, or servicing of "covered investment critical infrastructure" within the meaning of the DPA (where such activities are covered by column 2 of Appendix A to 31 C.F.R. Part 800); or (c) the maintenance or collection, directly or indirectly, of "**sensitive personal data**" of U.S. citizens within the meaning of the DPA. The Company has no current intention of engaging in such activities in the future.

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George O'Brien is a partner in Mayer Brown's Washington DC office and a member of the Corporate & Securities practice. He works with life sciences companies of all sizes to assist them in developing and marketing innovative products that are regulated by the US Food and Drug Administration, including drugs and biologics, medical devices, drug-device combination products, CBD and botanical products, medical foods and dietary supplements.

George has deep experience providing regulatory advice to pharmaceutical and biotech companies on lifecycle management issues, including regulatory exclusivities and FDA-facing patent issues. He is a leading expert on orphan drug matters, including orphan designation and exclusivity, and has successfully advocated on behalf of clients to FDA on matters related to prevalence, orphan subsets, and clinical superiority. George also regularly advises pharmaceutical and biotechnology companies on pediatric study and pediatric exclusivity issues arising under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

George has an active practice drafting citizen petitions and has obtained key victories for his clients on several issues, including bioequivalence and approval requirements for generic drug products, the operation of 180-day exclusivity, and therapeutic equivalence issues, as well as a groundbreaking petition that persuaded FDA to expand its application of new chemical entity exclusivity to fixed-dose combination drug products.

George regularly works with life sciences clients on FDA-facing patent issues. As part of this practice, he routinely assists clients on the submission of patent information to FDA's Orange Book and Purple Book. George also works closely with his IP colleagues during the entire Hatch-Waxman litigation process to ensure that intellectual property protections and regulatory strategies are aligned throughout a product's lifecycle.

George previously served on the Food and Drug Law Institute's Drugs & Biologics Committee. He regularly speaks and writes on FDA life sciences issues at FDLI's annual conference and elsewhere.

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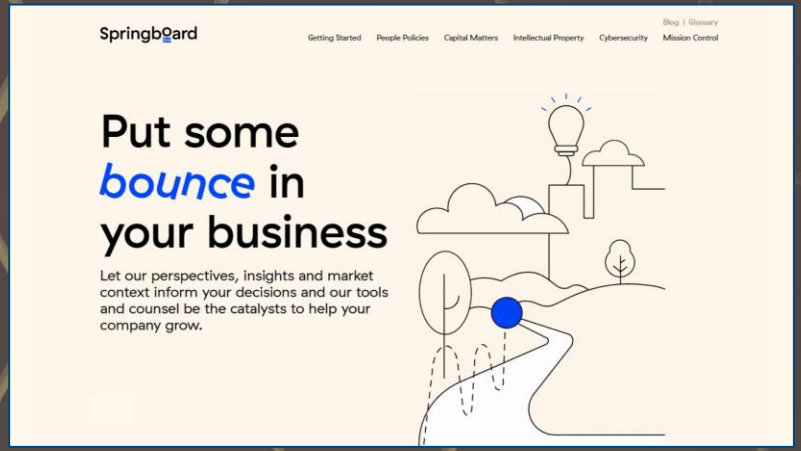
Mark Bonham is a partner in the Salt Lake City office of Mayer Brown and a member of the Emerging Companies & Venture Capital, Capital Markets, and Mergers & Acquisitions practices. Mark is also part of the Life Sciences and Technology industry groups. Mark focuses his practice on providing legal counsel to technology, life sciences, software and internet-based companies and the venture capital funds and strategic investors that finance these companies. Even while living and practicing in Silicon Valley, Mark became well-known in the Salt Lake City region beginning in the 1990s as a result of working with a variety of technology-driven businesses such as Novell, WordPerfect, MyFamily.com (predecessor to Ancestry), Sonic Innovations, and CardioPulmonics. He was involved in venture capital financings, M&A, and public offerings for these and other Utah-based companies. With a depth of knowledge in startups, venture financing, licensing, mergers and acquisitions, business strategy, corporate governance, IPOs, SEC reporting and exit strategy, Mark has deep relationships with tech startups and emerging companies.

Mark lives in Utah and was formerly a partner with two large regional law firms, where he served corporate law clients for over 20 years in California and Utah. He co-managed a group of 16 lawyers, and at various times served on the Compensation and Investment Committees, co-chaired the Recruiting Committee, and co-chaired the Knowledge Management Committee for one of those firms.

Mark has also served as a director of an NYSE-listed software company, where he was chairman of its Nominating and Governance Committee and a member of the Audit Committee, and where he developed an innovative director survey and rating methodology. He and four other executives formed a business consultancy, SageCreek Partners LLC, which advised technology companies in all stages of business from startup to growth and succession.

Additional Resources



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