| ***Speaker:* Demetrius Carter**  **Regulatory Affairs Executive, Certara**  **By: Melissa Growney**  In a seminar that was both sobering and insightful, Demetrius Carter, former president of Certara and current SVP of Regulatory Sciences at Certara, explored the deep-rooted challenges and obligations tied to clinical trial disclosure and transparency. This presentation tackled the ethical and regulatory frameworks that govern clinical research and the uncomfortable realities that can undermine public trust in science and the scientific process.  Demetrius began by revisiting the ethical cornerstones of modern clinical research, drawing connections between historical injustices, such as those revealed in the Nuremberg Trials post-World War II, which were subsequently addressed by the Declaration of Helsinki, reflected in the current ICH/GCP guidance documents. “In the spirit of research," he warned, is not a justification for ethical shortcuts. Medical writers, regulatory professionals, and researchers alike must remember that every data point represents a person, and each professional within this field carries a responsibility for how clinical work is represented. The legacy of unethical studies serves as a stark reminder that transparency is an obligation of the highest order.  The discussion then shifted to the complex and evolving landscape of clinical trial disclosure requirements. Demetrius emphasized that selective reporting and data cherry-picking are not only scientifically irresponsible but also unacceptable in the eyes of regulators and publishers. In fact, most reputable journals and regulatory authorities now require full data transparency, including the registration of trials and the reporting of both positive and negative outcomes. He challenged attendees to consider the systemic forces that lead to non-disclosure. Is it pressure to produce | favorable outcomes? Fear of regulatory consequences? Or simply the inertia of outdated practices? Regardless of the cause, the consequence is clear: eroded public trust and a growing skepticism about the pharmaceutical industry's intentions.  A key takeaway from Demetrius’ talk was the lack of harmonization across global regulatory bodies. While the intent to increase transparency is shared across agencies like the FDA, EMA, and Health Canada, inconsistent guidelines can breed confusion and create opportunities for strategic loopholes to work against accountability in this space. This disjointedness contributes to the public perception of opacity and makes the work of medical writers and regulatory professionals even more challenging.  So, what is "the good" in all of this? According to Demetrius, the rising awareness and push for reform within the industry itself aim to promote collaboration among regulators, advocating for data transparency without stifling innovation on a global scale. Medical writers are uniquely positioned to advocate for transparency by ensuring data is complete, accessible, and ethically framed.  For conference attendees, Demetrius' message was clear: our words hold power. In a time when scientific trust is fragile, the clarity, completeness, and ethical integrity of our writing are more critical than ever. Whether contributing to a clinical study report, trial registry entry, or publication, writers must help ensure that no truth is buried and no patient is forgotten. If there is one thing I took away from this seminar, it is that transparency is not just a checkbox; it is a mindset that is imperative for medical writers and clinical research professionals to adopt to ensure the integrity of all scientific research. |
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