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Data transparency and clinical trial disclosure: Medical communicator's perspective

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Disclosure and publishing of results is critical for advancement of science whether the trial results are positive or negative. The disclosures are important because they are the legal requirements, ethical responsibilities, industry commitments, impacts ability to publish, supports research and avoids duplication of research. Currently the disclosures are voluntary and the scene is changing every day to accommodate and streamline the requirements and execution by healthcare, pharmaceutical companies, clinical research organizations and medical communication companies. The current presentation enumerates all the documents that are required in this rapidly changing space and what are the recent advancements in this area which can expedite the documentation and transparency methods. This changing atmosphere and surroundings has contributed to an additional responsibility for the medical communication companies to develop medical and regulatory documents which can support the regulatory bodies, pharmaceutical and biotech companies to fulfill the disclosure requirements and maintain the required transparency. The key documents that fall under this category are: Clinical trial registration and status reporting, trial results posting, redaction of confidential company information, publication of trial results in journals, lay summaries for public and clinical overview and clinical summary. If all this documentation is done manually, then the amount of time and resource required is magnanimous. There are some new technologies available like automatic authoring and artificial intelligence which can play a great role in expediting these document requirements and reaching the goals of complete transparency and public disclosures globally and regionally. Now is the time for the whole research community to join hands and contribute in this ambitious endeavor to gain the best from the drug research and development and contribute to improved patient care and quality of life.

Biography

Namrata Singh has completed her MBBS degree in 1996 and was trained in Pediatrics from Sir Ganga Ram Hospital, India. She has a rich clinical experience of handling patients, patients' data and contributing to research. She has been working as a Medical Writer for 8 years in different roles as an employee, as Freelancer and currently as Head of a team of medical writers at Turacoz Healthcare Solutions, India. She has written for all major therapies and provided support for all publication documents like original research, review, case reports, case series, systematic reviews and meta-analysis.

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