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How fake clinical trials impact patient safety

Clinical trials are key to advancing evidence-based medical research, one of the pillars of the evidence-based medicine widely used to treat patient. While regulation is needed to ensure the conduct of clinical trials in compliance with ethical standards, with clear scientific proof and benefit overweigh risk to protect patient, fake trials and (subsequent) wrong publications can lead to wrong or ineffective or harmful molecules being brought in the market, hence have an impact on patient health. A literature review has been performed to identify situations where omitted data, altered data, manufactured data, misinterpretation of data and provision of wrong information were reported; solutions to address these situations have been also sought.

Speaker Biography

Danielle IWANDZA is the founder and CEO of PharmaCqARE, a cabinet providing drug-related counsel, training and services for pharmaceutical companies, authorities and healthcare professionals; she has 21 years of experience in the European pharmaceutical industry. She has been an independent pharmacovigilance senior consultant for 7 years, providing her services to medium sized and big pharma companies in France, Germany, Switzerland and The Netherlands. Prior to that, she had growing pharmacovigilance responsibilities and has been head of pharmacovigilance in France for a big pharma company and pharmacovigilance head & EU-QPPV for a hospital generic company. She was previously physician clinical research for 3 years and prior to that had been a medical practitioner in hospitals and clinics in the south of France. She graduated in the specialty of dermatology from the University of Montpellier in France. She also holds a clinical research degree from Sup'Santé school in Paris and a pharmacoepidemiology degree from the Bordeaux school of Pharmacy.

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