Abstract

The Center for Drug Safety Science (CDSS) aims to coordinate the fundamental clinical and basic research into the causes, characteristics, and consequences of adverse drug reactions (ADRs). It was established as a joint venture between the Universities of Liverpool and Manchester to bring together a critical mass of knowledge and technologies in order to advance understanding of ADRs.

Mission

The CDSS mission is to use the critical mass and knowledge in drug safety science that has accrued within the center to undertake leading-edge science and to train the next generation of drug safety scientists to understand the fundamental mechanisms of clinically important, and currently relevant, ADRs to develop strategies to improve the benefit-risk ratio of current and new medicines, for the benefit of patients, industry, and regulators.

By “closing the loop” on the mechanisms of ADRs, CDSS hopes to accelerate the ability to (a) inform the medicinal chemist with respect to drug design at an early stage in development; (b) advise the doctor and patient on safe drug selection; (c) advise regulation and industry; (d) improve the training of
scientists, clinicians, and regulators in drug safety science; and (e) improve communication in drug safety science in order to inform the public about the balance between potential risks and benefit of any medicine.

Structure & Governance

CDSS is led by a director (Kevin Park, B.Sc., Ph.D., Hon MRCP, FMEDSci), deputy director (Munir Pirmohamed, Ph.D., FRCP, FRCP(E)), and a Manchester lead (Ian Kimber).

An Executive Committee has overall responsibility for managing CDSS and provides oversight that includes (a) identifying specific ADR issues for further mechanistic evaluation and producing proposals for review by the Steering Group; (b) constructing appropriate cross-disciplinary teams for each research program; (c) day-to-day managing of active research programs; (d) effective coordinating of Universities of Liverpool and Manchester resources to ensure progression of research programs; (e) managing the MRes in drug safety science; (f) ensuring that CDSS becomes a focal point for the provision of drug safety science training to academic, industry, and government scientists; (g) defining and progressing an effective communication strategy; and (h) identifying additional funding resources and coordinating appropriate grant applications.

The Steering Group is responsible for advising on the overall scientific strategy and direction of CDSS in the context of the changing problems and research priorities in drug safety. Responsibilities include (a) providing advice on specific ADR issues that the Executive Committee has defined for further mechanistic evaluation; (b) providing appropriate resources for research programs to ensure effective implementation and productivity; and (c) ensuring that CDSS training and communication strategies are being effectively implemented.

The Scientific Advisory Board is responsible for providing high-level strategic input and expertise to complement the CDSS strategy, vision, and objectives. Current members include Tom Baillie, dean, School of Pharmacy, University of Washington; Sir Gordon W. Duff (M.A., B.M., B.Ch., Ph.D., FRCP, FRCPE, FMedSci), director, Division of Genomic Medicine, School of Medicine and Biomedical Sciences, University of Sheffield; Garret Fitzgerald, director, Institute for Translational Medicine and Therapeutics, University of Pennsylvania; Magnus Ingelman-Sundberg, professor of molecular toxicology, Department of Physiology and Pharmacology, Karolinska Institute; Gregory Kearns, professor of pediatrics and pharmacology, division chief, clinical pharmacology and medical toxicology,
and director, Pediatric Pharmacology Research Unit, The Children’s Mercy Hospitals and Clinics, Kansas City, Missouri; Thomas Lööngren, executive director, European Medicines Agency; Sir Alex Markham, professor of medicine, Leeds Institute of Molecular Medicine; and Paul Watkins, professor of medicine, professor of toxicology, and professor of experimental therapeutics, University of North Carolina at Chapel Hill, and director, Center for Drug Safety Science, Hamner Institute

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