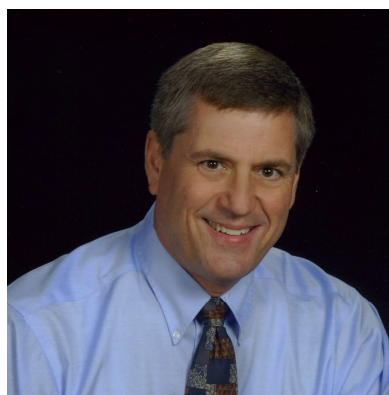


## Meet the Network and Community Leadership

### Network: Development, Regulatory, & Outcomes (DRO)



**Network Vice Chair:**  
**Donald L. Heald, PhD**  
Janssen R&D

Donald Heald completed his Master's and PhD degrees in Pharmacology and Pharmaceutical Sciences at West Virginia University. After completing a sabbatical at the Theoretical Mathematical Biology Department at the National Cancer Institute at NIH, Dr. Heald joined the FDA as a Biopharmaceutics Reviewer for the Cardio-Renal Division. While at the agency, he also developed and applied the first application of the electronic NDA (CANDA). Dr. Heald then joined The Upjohn Company as a Senior Research Scientist providing clinical pharmacology (CP) support for the development of anti-cancer and anti-aids drugs. He joined Rorer Pharmaceuticals to build a bioanalytical/methods development, clinical pharmacology and modeling groups and eventually lead the Clinical Drug Disposition Department at Rhone Poulenc Rorer (RPR) which supported all global projects in R&D. After 8 years, he left R&D to become Director of CP in Medical Affairs at RPR. Working together with the PET imaging center at Case Western Reserve, the team developed novel nuclear imaging techniques to determine lung and intranasal deposition of drugs. In 2000, he joined Johnson & Johnson as the Head of Clinical Pharmacokinetics (CPK) for Janssen Research Foundation and in 2002, he was appointed Global Head of CPK in J&J Pharmaceutical Research and Development and his group was responsible for all CP programs in all therapeutic areas. In 2009, the department restructured into therapeutic areas and Don was the CP Therapeutic Area Head for Neurosciences. Don sponsored a cross functional 3-year effort to investigate the translational aspects to assess blood-brain barrier drug transport which won the Innovation Leadership and Campus Excellence awards. This effort led to submission and approval of a 1.6 million euro IWT grant to further study the translation from rodent to patients. In December 2014, he joined Biologics Clinical Pharmacology (BCP) in Janssen Biotherapeutics and is currently responsible for Early Development (Translational Sciences and Preclinical Development) and Strategic Reviews for all biologics compounds in all therapeutic areas. He has over 50 publications, 60 poster presentations and an invited speaker over 40 times. Don is currently the Vice-Chair for the DRO Network and was actively involved on the Scientific Planning Committee for ASCPT.