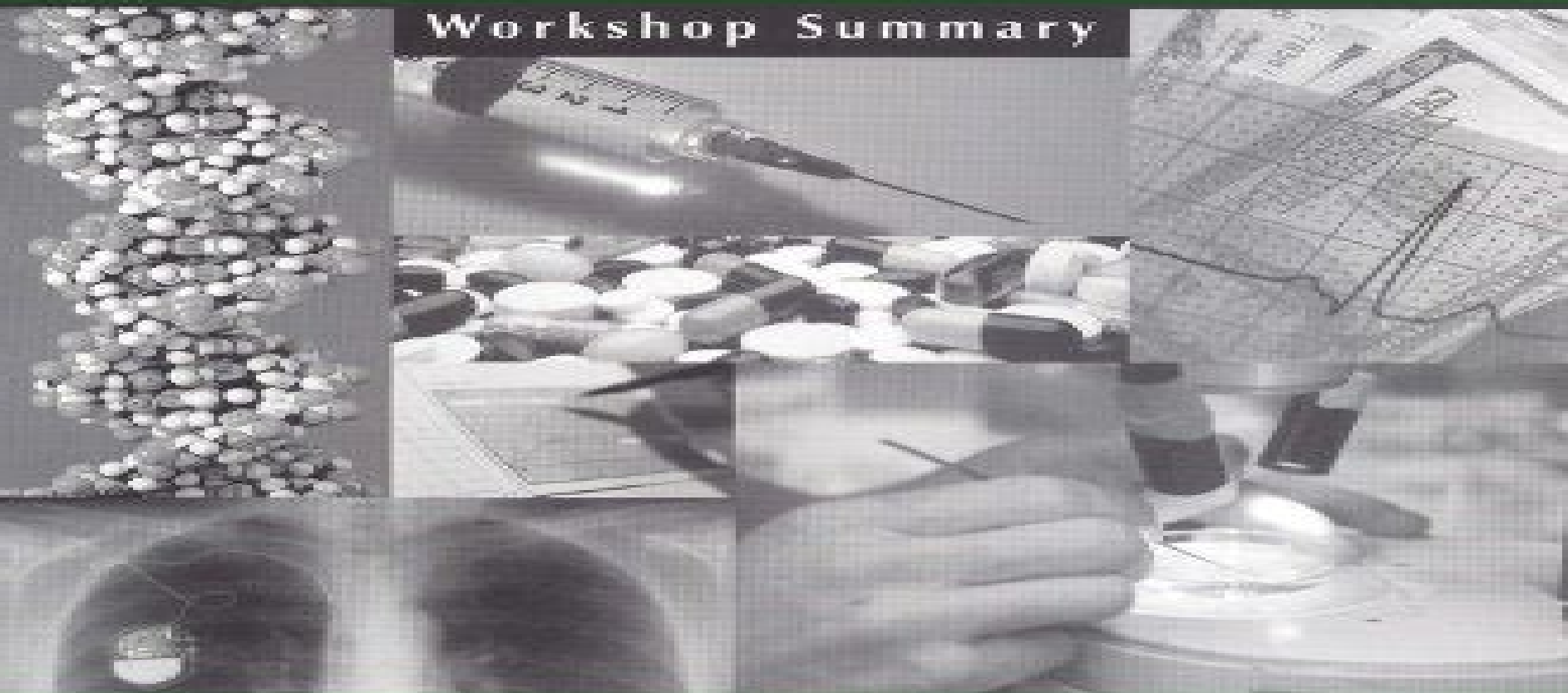


# Rational Therapeutics for Infants and Children

## Workshop Summary



# Rational Therapeutics For Infants And Children Workshop Summary

**Arturo Cuomo**



## **Rational Therapeutics For Infants And Children Workshop Summary:**

Rational Therapeutics for Infants and Children Roundtable on Research and Development of Drugs Biologics and Medical Devices, Division of Health Sciences Policy, Institute Of Medicine, 2000-04-07 The Institute of Medicine's IOM's Roundtable on Research and Development of Drugs Biologics and Medical Devices evolved from the Forum on Drug Development which was established in 1986. Sponsor representatives and IOM determined the importance of maintaining a neutral setting for discussions regarding long term and politically sensitive issues justified the need to revise and enhance past efforts. The new Roundtable is intended to be a mechanism by which a broad group of experts from the public and private sectors can be convened to conduct a dialogue and exchange information related to the development of drugs biologics and medical devices. Members have expertise in clinical medicine pediatrics clinical pharmacology health policy health insurance industrial management and product development and they represent interests that address all facets of public policy issues. From time to time the Roundtable requests that a workshop be conducted for the purpose of exploring a specific topic in detail and obtaining the views of additional experts. The first workshop for the Roundtable was held on April 14 and 15 1998 and was entitled Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making. The summary on that workshop is available from IOM. This workshop summary covers the second workshop which was held on May 24 and 25 1999 and which was aimed at facilitating the development and proper use of drugs biologics and medical devices for infants and children. It explores the scientific underpinnings and clinical needs as well as the regulatory legal and ethical issues raised by this area of research and development.

**Rational Therapeutics for Infants and Children** Institute of Medicine, Division of Health Sciences Policy, Roundtable on Research and Development of Drugs, Biologics, and Medical Devices, Jonathan R. Davis, Sarah Pitluck, Peter Boussein, Ronald W. Estabrook, 2000-05-07 The Institute of Medicine's IOM's Roundtable on Research and Development of Drugs Biologics and Medical Devices evolved from the Forum on Drug Development which was established in 1986. Sponsor representatives and IOM determined the importance of maintaining a neutral setting for discussions regarding long term and politically sensitive issues justified the need to revise and enhance past efforts. The new Roundtable is intended to be a mechanism by which a broad group of experts from the public and private sectors can be convened to conduct a dialogue and exchange information related to the development of drugs biologics and medical devices. Members have expertise in clinical medicine pediatrics clinical pharmacology health policy health insurance industrial management and product development and they represent interests that address all facets of public policy issues. From time to time the Roundtable requests that a workshop be conducted for the purpose of exploring a specific topic in detail and obtaining the views of additional experts. The first workshop for the Roundtable was held on April 14 and 15 1998 and was entitled Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making. The summary on that workshop is available from IOM. This workshop summary covers the second workshop which was held on May 24 and 25 1999 and

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A Clinical Lens on Pediatric Engineering Jamie Leigh Wells, 2025-04-29 A Clinical Lens on Pediatric Engineering Pioneering Science and Technology for Cutting Edge Patient Care explores the depth and breadth of the newly applied science of pediatric engineering and its dawning era Placing into context the origins of pediatric medicine and engineering this deep dive into and beyond medical digital to device innovation integrates scientific rigor with clinical perspective incorporating case examples of diagnostic and therapeutic breakthroughs cautionary tales and lessons in translation The book begins by explaining the unique considerations of the developing child and the importance of including nuanced end user and human factors early and often in the process of seeking biomedical solutions It provides an overview of this population's diverse and dynamic biopsychosocial characteristics compared to adults contrasting organ systems cognitive maturation bioethics growth and drug metabolism A distinguished team of contributors supplies a comprehensive blueprint for transforming an idea through to clinical implementation featuring the ever expanding influences and intricacies of discovery The book covers a wide array of topics including fetal intervention transplantation regenerative medicine addiction ophthalmology surgery e g minimally invasive orthopedic cancer nanotechnology radiology imaging modalities

gene therapy artificial intelligence AI machine learning liquid biopsy immersive technologies e g augmented and virtual reality neurodiversity rare disease critical care robotics materials science and tissue engineering The design challenges specific to children s hospitals and healthcare facilities are discussed highlighting the flexibility needed to achieve optimal patient outcomes gather meaningful data and drive innovative progress This landmark work calls on key stakeholders to address the obstacles related to funding practices clinical trials and other impediments that hinder the timely and safe delivery of life altering and life saving results It provides child health innovators with the essential tools to bridge these gaps and drive transformation in the rapidly evolving landscape of pediatric care

Ethical Conduct of Clinical Research Involving Children Institute of Medicine, Board on Health Sciences Policy, Committee on Clinical Research Involving Children, 2004-08-09 In recent decades advances in biomedical research have helped save or lengthen the lives of children around the world With improved therapies child and adolescent mortality rates have decreased significantly in the last half century Despite these advances pediatricians and others argue that children have not shared equally with adults in biomedical advances Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research we do not want to place children at risk of being harmed by participating in clinical studies Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it It also considers problems with the interpretation and application of these standards and conduct concluding that while children should not be excluded from potentially beneficial clinical studies some research that is ethically permissible for adults is not acceptable for children who usually do not have the legal capacity or maturity to make informed decisions about research participation The book looks at the need for appropriate pediatric expertise at all stages of the design review and conduct of a research project to effectively implement policies to protect children It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular

**An Examination of Pediatric Drug Testing** Victoria J. Isada, 2003 **Toxic Chemical and Biological Agents** Giovanni Sindona, Joseph H. Banoub, Maria Luisa Di Gioia, 2020-10-19 This book critically assesses the current state of knowledge on new and important detection technologies e g mass spectrometry tandem mass spectrometry biosensor detection and tissue imaging in connection with toxic chemical and biological agents In general the main topics discussed concern the risks and consequences of chemical and biological agents for human health in general with special emphasis on all biochemical and metabolic pathways including the reproductive system The exposome genetic risks and the environment various health hazard agents risk assessment environmental assessment and preparedness and analysis of sub lethal effects at the molecular level are also discussed In closing the book provides comprehensive information on the diagnosis of exposure and on health concerns related to toxic chemical and biological agents

*Innovation and Invention in Medical Devices* Institute

of Medicine, Board on Health Sciences Policy, Roundtable on Research and Development of Drugs, Biologics, and Medical Devices, 2001-12-01 The objective of the workshop that is the subject of this summary report was to present the challenges and opportunities for medical devices as perceived by the key stakeholders in the field The agenda and hence the summaries of the presentations that were made in the workshop and which are presented in this summary report was organized to first examine the nature of innovation in the field and the social and economic infrastructure that supports such innovation The next objective was to identify and discuss the greatest unmet clinical needs with a futuristic view of technologies that might meet those needs And finally consideration was given to the barriers to the application of new technologies to meet clinical needs *Neonatal Medications & Nutrition* Karin E. Zenk, Jack H. Sills, Robin M. Koepfel, 2003 **Books In Print**

**2004-2005** Ed Bowker Staff, Staff Bowker, Ed, 2004 **Controversies in Growth Hormone Treatment and Diagnosis**  
Robert Rapaport, Martin Oswald Savage, 2022-10-25 **Cumulated Index Medicus**, 1989 **Index Medicus**, 2003 Vols  
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