

Request for Information: FDA-NIH Resource on Terminology for Clinical Research

Introduction

To address the lack of consistency in the use of clinical research terms, the National Institutes of Health (NIH) and U.S. Food and Drug Administration (FDA) have issued a joint Request for Information (RFI) to solicit input on an initiative to clarify clinical research terms related to innovative clinical study designs.

We thank the National Institutes of Health and the Food and Drug Administration for the opportunity to provide comments for NOT-24-112: FDA-NIH Resource on Terminology for Clinical Research. Below is the Endocrine Society's response to question number three "Other pertinent terms that are inconsistently used within the scientific community."

<u>Clinical Research Term</u>	<u>Proposed Definition</u>	<u>Rationale</u>	<u>Suggested Definition Source</u>
Quantitative Structure-Activity Relationship (QSAR)	Theoretical models that relate a quantitative measure of chemical structure to a physical property, or a biological activity	Related to estrogen/testosterone binding used in endocrine disrupting chemical (EDC) research and useful in understanding EDC toxicology.	https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=536485&Lab=NCCT
Structure Activity Relationship (SAR)	An approach to find qualitative relationships between chemical structure and their biological activity	Related to estrogen/testosterone binding used in endocrine disrupting chemical (EDC) research and useful in understanding EDC toxicology.	https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=536485&Lab=NCCT
Decision Forest Model	A novel pattern-recognition method which can be used to analyze: <ul style="list-style-type: none"> DNA microarray data Surface-Enhanced Laser Desorption/Ionization 	Related to estrogen/testosterone binding used in endocrine disrupting chemical (EDC) research and useful in understanding EDC toxicology.	https://www.fda.gov/science-research/bioinformatics-tools/decision-forest



	<p>n Time-of-Flight Mass Spectrometry (SELDI-TOF-MS) data</p> <ul style="list-style-type: none"> • Structure-Activity Relation (SAR) data 		
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Crossover study	A type of clinical trial in which all participants receive the same two or more treatments, but the order in which they receive them depends on the group to which they are randomly assigned. For example, one group is randomly assigned to receive drug A followed by drug B. The other group receives drug B followed by drug A. There is usually a rest period between treatments.	Related to the methodology used in designing clinical trials.	https://www.cancer.gov/publications/dictionaries/cancer-terms/def/crossover-study
Confirmation bias	As the term is typically used in psychological literature, connotes the seeking or interpreting of evidence in ways that are partial to existing beliefs, expectations, or a hypothesis in hand. The author reviews evidence of such a bias in a variety of guises and gives examples of its operation in several practical contexts. Possible explanations are considered, and the question of its utility or disutility is discussed.	Recognition and acknowledgement of potential biases can improve experimental designs and reduce error in data analyses.	https://journals.sagepub.com/doi/10.1037/1089-2680.2.2.175
Electronic Medical Record (EMR)	Electronic medical record (EMR) systems, defined as "an electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by	Related to digital methods of storing and organizing patient and research information.	https://digital.ahrq.gov/electronic-medical-record-systems



	authorized clinicians and staff within one health care organization”, have the potential to provide substantial benefits to physicians, clinic practices, and health care organizations.		
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Health+ Human-Centered Design	Health+ is a series of ongoing research and rapid prototyping cycles applied to specific, high-impact health issues. Each cycle begins with involving the people and communities affected and placing them at the center of the problem-solving process and solution: putting people first by conducting desk research, interviews, focus groups, and listening to the challenges they face.	Human-centered design methods such as interviews, listening sessions, and workshops are used to meaningfully engage the people and communities impacted and build trust.	https://www.hhs.gov/ash/osm/innovationx/human-centered-design/index.html
Implementation science	Implementation science (IS) is the study of methods to promote the adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings to improve our impact on population health.	The term encourages clinical researchers, particularly clinical trialists, to consider downstream application at the population level in their research design. Inclusion of this term should reduce delays in transitioning pivotal clinical research results to practice within the context of health systems for the populations and diseases being studied.	https://cancercontrol.cancer.gov/is/about