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Letter to the Editor

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Investigator-Initiated vs. Investigator-Sponsored Research: Definitions Matter

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To the Editor

Investigator-initiated trials (IITs), investigator-initiated studies (IISs), investigator-sponsored trials (ISTs), investigator-initiated research (IIR), non-registration trials (NRTs), non-sponsored trials, academic clinical trials, physician-led studies, investigator-driven clinical trials, and academic studies are only some of the terms used to describe research developed at the "site" level for which an individual, most often the principal investigator, is the one who conceives of and develops a research protocol, with or without support. Though these terms are often used interchangeably, they do not always describe the same concept. This lack of clarity ought to be addressed and we suggest that a single term: investigator-initiated (II) be employed to describe these situations. Issues are further perplexed when trying to identify the funding source based on the term used. To begin, consider the second part of the aforementioned terms. The term "trials", as opposed to "studies" or "research", specifies the type of a project. If accurately used, it should reflect actual clinical trials as per the regulatory definition, i.e. interventional studies [1] as opposed to "studies" that include both interventional and observational projects. The term "research", often a synonym of "studies", is also used to include all types of projects and can be used as the "umbrella" term to ensure the inclusion of any type of study.

The most commonly used terms in this space are investigator-initiated and investigator-sponsored. Based on a PubMed [2] search, the term "investigator-initiated" appeared for the first time in a published (PubMed indexed) paper in 1979 and was infrequently used until 2010, while the less used term "investigator-sponsored" appeared in 1987 and was not integrated into the mainstream terminology until 2015 - 2016. Though some use these terms are considered by many to be synonymous or refer to the same concept, we argue that "initiated" and "sponsored" capture different characteristics of these projects and should not be used interchangeably. Initiated suggests that the conception of the idea and the protocol development are led by an individual, while "sponsored", often used inaccurately to describe the funding source, according to its regulatory definition, refers to the individual or entity that assumes the regulatory responsibilities, e.g. registration, monitoring, etc. Whether medical, academic, or research, many institutions assume the regulatory responsibilities of the sponsor instead of passing those to the investigator, who conceived the study and developed the study protocol. In such cases, studies are investigator-initiated, institution-sponsored with or without external funding (which complicates matters further). Similarly, to the confusion between sponsored and initiated, we also observe the lack of clarity regarding the use of the terms "sponsored" and "funded". Many of these projects are often supported financially (or in kind) by industry (e.g., when a drug is provided free of charge) or other entities (e.g., when private or federal funding is offered). In those cases, the most appropriate term would be "investigator-initiated (institution-sponsored) funded", reflecting the three different roles relevant to the research and the responsibilities assumed: investigator, sponsor, and funding body.

In conclusion, we believe that the term "investigator-initiated" reflects more accurately the majority of the "home-grown" ideas that are conceived by an individual who in most cases is not the project's regulatory sponsor, and so we propose it be used. Using the term consistently would minimize confusion and ensure a level of consistency and transparency while facilitating communications between sites, funding bodies, and the federal authorities.

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Informed Consent

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Data Availability

The authors declare that data supporting the findings of this study are available within the article.

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