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Nanotechnologies — Framework for identifying vocabulary development for nanotechnology applications in human healthcare

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National foreword

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TECHNICAL REPORT

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Nanotechnologies — Framework for identifying vocabulary development for nanotechnology applications in human healthcare

Nanotechnologies — Cadre pour le développement d'un vocabulaire d'identification des applications de nanotechnologies en santé humaine

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Foreword

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The committee responsible for this document is ISO/TC 229, *Nanotechnologies*.

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Introduction

Terminology related to the use of nanotechnologies in human healthcare is on the rise as research in the field continues to intensify. The heightened focus in medical research on nanotechnologies is reflected by the number of medical and related scientific journals that are reporting on this research. The number of publications mentioning both nanotechnology and biology or medicine has increased logarithmically since approximately the year 2000.[1]

This Technical Report explains current concepts related to human healthcare in the clinical setting and identifies pertinent and timely categories most likely to be advanced by nanotechnologies. Certain aspects of human healthcare are expected to be advanced by nanotechnologies more than others, and standardization needs unique vocabulary to support the development of applications of nanotechnologies within it. It is recognized, for example, that physical chemists use the term "substrate" to describe a material surface supporting adsorption processes; this differs from a biologist's use of the term "substrate" to describe a substance that an enzyme acts upon.

Due to the keen public interest in the advancement of human healthcare, a common vocabulary is particularly relevant to the development of research proposals to gain funding and to communicate findings and results. This Technical Report provides a taxonomic framework to serve as the basis for the development of terminology related to the application of nanotechnologies in human healthcare. The framework identifies categories associated with the clinical value chain most likely to be advanced by nanotechnologies and describes some of the promising technologies being developed and utilized within the clinical workflow. It is intended that terms will be identified and harmonized definitions will be developed for them within the framework offered by this Technical Report.

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Nanotechnologies — Framework for identifying vocabulary development for nanotechnology applications in human healthcare

1 Scope

This Technical Report will not attempt a formal, comprehensive definition of "nanomedicine". Instead, it will provide a taxonomic framework for the development of vocabulary for clinical applications of nanotechnologies in human healthcare. While it is understood that the origins of nanotechnologies for healthcare applications emerge from pre-clinical and translational research, the interest of this Technical Report is to determine where these technologies will impact the clinical value chain and the practice of medicine.

This Technical Report is intended to facilitate communications between developers and users of nanotechnologies, deliverers and users of medicine including the pharmaceutical, research and medical communities, regulatory professionals, and additional organizations and individuals who might interact with these groups, including biotechnology, diagnostic, and medical device companies, the life sciences, patent attorneys and patent offices, institutional review boards, ethics review boards, and accreditation organizations.

2 Symbols and abbreviated terms

nm nanometer

3 Framework

3.1 General

The term "nanomedicine" is used by the scientific community and government agencies to describe a field that is relatively undefined in terms of the affected health care segments and the specific advances in nanotechnologies for biomedical applications.

In addition, the relevant mechanisms currently associated with diagnosis and treatment in biological processes can be larger than approximately 100 nm (e.g. endocytosis). Several participants from the biological sciences work with 400 nm diameter particles as drug carriers, while others consider <1 000 nm or <500 nm as pertinent in exploring emerging applications. Overall, the products currently enabled by nanotechnologies that are available for commercial clinical use are characterized by *in vitro* bulk properties or systemic effects. Examples of nanosize objects of interest in healthcare applications are depicted in Figure 1.

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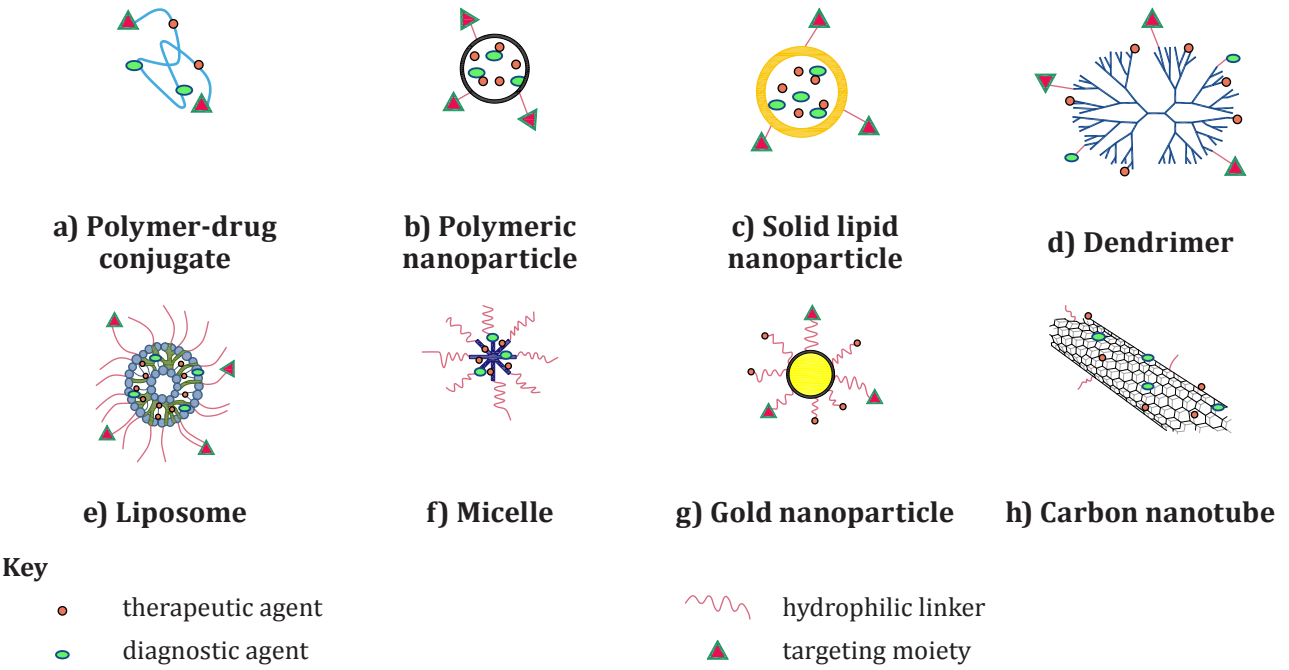

Figure 1 — Examples of nanosize objects of interest in healthcare applications[2]

In contrast, the current ISO definition of the term "nanoscale" stems from materials science and expresses in part the size range associated with quantum effects. The broad, enabling nature of nanotechnologies means that convergence with the biological sciences will continue to intensify. However, this Technical Report does not seek to suggest that current definitions in nanotechnologies, such as the approximately 100 nm upper boundary found in the ISO definition of the term "nanoscale",[3] be normalized to account for all size relationships in biological systems.

3.2 The clinical value chain

3.2.1 General

In recognition of the advancements that are anticipated in the clinical practice of medicine associated with nanotechnologies, relevant applications of nanotechnologies in human healthcare can be identified by their location in the clinical value chain (see Figure 2).

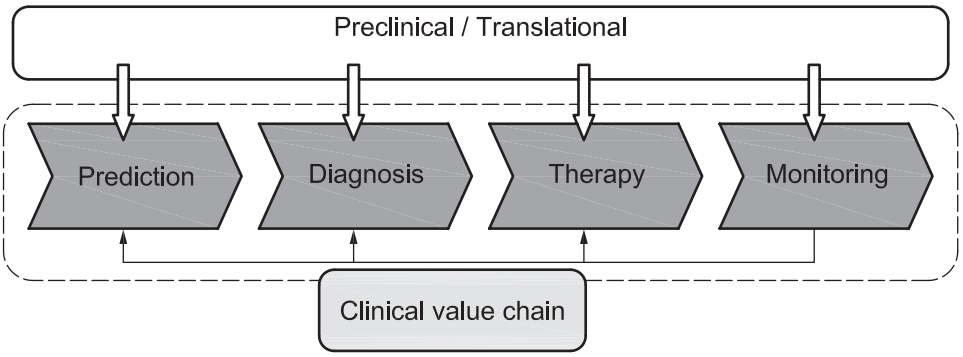

Figure 2 — The clinical value chain

The clinical value chain suggested for use in this Technical Report consists of 4 segments. The prediction and prevention segment includes nanotechnologies that are used to predict, or prevent

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