



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of ISO/TR 17302:2015.

The UK participation in its preparation was entrusted to Technical Committee NTI/1, Nanotechnologies.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015.

Published by BSI Standards Limited 2015

ISBN 978 0 580 76119 5

ICS 07.030

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 December 2015.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

TECHNICAL
REPORT

ISO/TR
17302

First edition
2015-12-15

**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*



Reference number
ISO/TR 17302:2015(E)

© ISO 2015



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015. Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Symbols and abbreviated terms	1
3 Framework	1
3.1 General.....	1
3.2 The clinical value chain.....	2
3.2.1 General.....	2
3.2.2 Prediction and prevention.....	3
3.2.3 Diagnosis.....	4
3.2.4 Therapy.....	5
3.2.5 Monitoring.....	5
4 Terminology development within the clinical value chain	6
4.1 General.....	6
4.2 Identifying terms in need of definition in the clinical value chain.....	7
4.2.1 General.....	7
4.2.2 Prediction and prevention.....	8
4.2.3 Diagnosis.....	8
4.2.4 Therapy.....	9
4.2.5 Monitoring.....	9
4.2.6 Further identification of potential terms.....	9
Annex A (informative) Nanomedicine terms as defined in current literature	10
Annex B (informative) Nanomedicine ontology and terminology resources	16
Bibliography	18

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

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

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.

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](#).