



DPC: 25/30466216 DC

**BSI Group Headquarters**

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 15 December 2025

Origin: European

**Latest date for receipt of comments: 07 February 2026**

Project No. 2022/02737

Responsible committee: CH/194 Biological evaluation of medical devices

Interested committees:

Title: Draft BS EN ISO 18969 Clinical evaluation of medical devices.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 07 February 2026**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email [cservices@bsigroup.com](mailto:cservices@bsigroup.com). British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

Responsible Committee Secretary: Mr Alastair Holmes (BSI)

Direct tel:

E-mail: [alastair.holmes@bsigroup.com](mailto:alastair.holmes@bsigroup.com)

Full document details: 25/30466216 DC

## Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

## UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

## Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

## Template for comments and secretariat observations

|                  |                        |
|------------------|------------------------|
| Date: xx/xx/20xx | Document: ISO/DIS xxxx |
|------------------|------------------------|

| 1  | 2                                          | (3)                          | 4               | 5                                                                                                                                  | (6)                                                                      | 7                                                  |
|----|--------------------------------------------|------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/ Figure/Table/Note | Type of comment | Comment (justification for change) by the MB                                                                                       | Proposed change by the MB                                                | Secretariat observations on each comment submitted |
|    | 3.1                                        | Definition 1                 | ed              | Definition is ambiguous and needs clarifying.                                                                                      | Amend to read '...so that the mains connector to which no connection...' |                                                    |
|    | 6.4                                        | Paragraph 2                  | te              | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer.                                       |                                                    |



# DRAFT International Standard

## ISO/DIS 18969

### Clinical evaluation of medical devices

*Evaluation clinique des dispositifs médicaux*

ICS: 11.040.01

ISO/TC 194

Secretariat: **DIN**

Voting begins on:  
**2025-12-15**

Voting terminates on:  
**2026-03-09**

This document is circulated as received from the committee secretariat.

**ISO/CEN PARALLEL PROCESSING**

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

Reference number  
ISO/DIS 18969:2025(en)

Full document details: 25/30466216 DC

© ISO 2025  **Documents**  
Document Sharing Hub



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

|                                                                                                     |           |
|-----------------------------------------------------------------------------------------------------|-----------|
| <b>Foreword</b>                                                                                     | <b>v</b>  |
| <b>Introduction</b>                                                                                 | <b>vi</b> |
| <b>1 Scope</b>                                                                                      | <b>1</b>  |
| <b>2 Normative references</b>                                                                       | <b>1</b>  |
| <b>3 Terms and definitions</b>                                                                      | <b>1</b>  |
| <b>4 Symbols and Abbreviations</b>                                                                  | <b>5</b>  |
| <b>5 General requirements</b>                                                                       | <b>6</b>  |
| 5.1 Purpose of the clinical evaluation                                                              | 6         |
| 5.2 Management Responsibilities                                                                     | 7         |
| 5.3 Clinical evaluation process                                                                     | 7         |
| 5.4 Clinical evaluation quality management                                                          | 8         |
| 5.5 Competencies relevant for the clinical evaluation                                               | 9         |
| 5.6 Documentation of the clinical evaluation                                                        | 9         |
| <b>6 Clinical evaluation considerations throughout the life cycle</b>                               | <b>9</b>  |
| 6.1 Overall considerations                                                                          | 9         |
| 6.2 Planning considerations during design and development                                           | 10        |
| <b>7 Clinical evaluation planning</b>                                                               | <b>11</b> |
| 7.1 General                                                                                         | 11        |
| 7.2 Identifying medical and non-medical alternatives                                                | 12        |
| 7.3 Identification of data sources for available knowledge                                          | 13        |
| 7.4 Identification of data sources for the device under evaluation                                  | 14        |
| 7.4.1 Non-clinical data relevant to the device under evaluation                                     | 14        |
| 7.4.2 Clinical data relevant to the device under evaluation                                         | 14        |
| 7.5 Special considerations                                                                          | 15        |
| 7.5.1 Transferability of clinical data                                                              | 15        |
| 7.5.2 Medical devices with special clinical evaluation considerations                               | 15        |
| 7.5.3 Considerations for the level of clinical evidence                                             | 15        |
| <b>8 Clinical evaluation conduct and documenting</b>                                                | <b>16</b> |
| 8.1 Available knowledge                                                                             | 16        |
| 8.2 Device under evaluation                                                                         | 16        |
| 8.2.1 Data collection                                                                               | 16        |
| 8.2.2 Data appraisal                                                                                | 17        |
| 8.2.3 Data analysis and conclusions                                                                 | 17        |
| <b>9 Overall assessment</b>                                                                         | <b>18</b> |
| 9.1 General considerations                                                                          | 18        |
| 9.2 Safety                                                                                          | 18        |
| 9.3 Clinical performance or effectiveness, including clinical benefit(s)                            | 18        |
| 9.4 Benefit-risk profile                                                                            | 19        |
| 9.5 Limitations                                                                                     | 19        |
| <b>10 Final conclusions</b>                                                                         | <b>20</b> |
| <b>11 Additional activities</b>                                                                     | <b>20</b> |
| <b>12 Update of the clinical evaluation</b>                                                         | <b>21</b> |
| <b>Annex A (informative) Clinical evaluation documentation: suggested outline</b>                   | <b>22</b> |
| <b>Annex B (informative) Methodology for data search - literature search</b>                        | <b>27</b> |
| <b>Annex C (informative) Appraisal of data</b>                                                      | <b>30</b> |
| <b>Annex D (informative) Analysis of data</b>                                                       | <b>32</b> |
| <b>Annex E (informative) Clinical evaluation activities during medical device life cycle stages</b> | <b>33</b> |

|                                                                                                                                                |           |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>Annex ZA (informative) Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered</b> | <b>35</b> |
| <b>Bibliography</b>                                                                                                                            | <b>42</b> |

## 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](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document specifies a clinical evaluation process by which clinical evidence is obtained from the pre-clinical and clinical use of medical devices to verify their safety and clinical performance or effectiveness, including clinical benefit(s).

The readers of this document are encouraged take into account the importance of linking the clinical evaluation process into other processes, especially to design and development, risk management and regulatory strategy.

The flowcharts embedded in this document are intended to assist the readers in obtaining a better understanding of the activities associated with the clinical evaluation process during the medical device life cycle and especially supporting design and development.

The clinical evaluation process is an iterative and modular process. Not all requirements of this document apply to each device type or medical device life cycle phase.

For the purpose of this document, the use of the term compliance is applied when compliance to this document's requirements is required. In case of requirements outlined in regulatory documents or other standards, the term 'conformance with' is applied.

# Clinical evaluation of medical devices

## 1 Scope

This document specifies, principles and a process for the clinical evaluation of medical devices. This document specifies how to plan and perform clinical evaluation, including the collection, appraisal and analysis of data to assess the safety and, clinical performance or effectiveness, including clinical benefit(s) of medical devices, and to evaluate the acceptability of clinical risks when weighed against the clinical benefits achieved when the device under evaluation (DUE) is used as intended by the manufacturer. This includes the determination whether there is evidence for the assessment.

This document also:

- defines the responsibilities of the manufacturer and those conducting or contributing to a clinical evaluation on behalf of the manufacturer,
- assists manufacturers, regulatory authorities and other stakeholders involved in the process or assessment of the clinical evaluation of medical devices and,
- provides guidance on the scientific conduct of a clinical evaluation, thereby supporting the credibility of conclusions.

This document does not apply to in vitro diagnostic medical devices.

NOTE 1 National regulations can have additional or different requirements.

NOTE 2 Some of the principles of this document can apply to actors other than manufacturers involved in clinical evidence generation.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

## 3 Terms and definitions

For the purposes of this document, the *following terms and definitions* apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

### 3.1

#### **adverse event**

untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including abnormal laboratory findings) in patients, users or other persons, related to the DUE, independent of risk level and whether anticipated or unanticipated

Note 1 to entry: Regional definition may apply and override the meaning of this term.

[SOURCE: ISO 14155:2020, 3.2 - modified by replacing the 'investigational device' by 'DUE' and added 'independent of risk level'; Original notes have not been included]

### 3.2

#### **available knowledge**

known and accessible clinical and non-clinical information

Note 1 to entry: *State of the art* (3.28) is a subset of *available knowledge* (3.2).

### 3.3

#### **clinical benefit**

positive impact of a device on the health of an individual expressed in terms of a meaningful measurable patient-relevant *clinical outcome* (3.10)(s), including outcome(s) related to treatment, diagnosis, or a positive impact on patient management or public health

### 3.4

#### **clinical condition**

clinical, medical, physiological, or pathological condition the device is intended to treat, diagnose or manage

### 3.5

#### **clinical data**

information generated from the *clinical use* (3.14) of a medical device

### 3.6

#### **clinical development**

process to generate *clinical evidence* (3.8)

### 3.7

#### **clinical evaluation**

set of continuous activities that use scientifically sound methods for the assessment and analysis of *clinical data* (3.5) and relevant non-clinical data (3.5) to verify the *safety* (3.24) and *clinical performance* (3.12) or *effectiveness* (3.17), including *clinical benefit* (3.3) of the medical device when used as intended by the manufacturer

[SOURCE: IMDRF MDCE WG/N56final:2019; clinical evaluation<sup>[1]</sup>]

### 3.8

#### **clinical evidence**

*results of the evaluation of clinical data* (3.5) and relevant non-clinical data (3.5) pertaining to a medical device

[SOURCE: IMDRF MDCE WG/N56final:2019; clinical evaluation<sup>[1]</sup>]

### 3.9

#### **clinical investigation**

clinical trial

clinical study

systematic investigation in one or more human subjects, undertaken to assess the *safety* (3.24) and *clinical performance* (3.12) or *effectiveness* (3.17), including *clinical benefit(s)* (3.3) of a medical device

[SOURCE: ISO 14155:2020, 3.8 - modified by adding 'including clinical benefit(s)']

**3.10****clinical outcome**

measurable change in symptoms, overall health, ability to function, quality of life, or survival outcomes that result from giving care to patients or outcome in patient management

Note 1 to entry: For diagnostic devices, the *clinical outcome* (3.10) relates to the capability of providing accurate medical information on individuals, where appropriate, assessed with other available medical information, and where health management may be dependent on further diagnostic or therapeutic options which could be available for the healthcare professional.

Note 2 to entry: For devices intended for patient management, the clinical outcomes can relate to reliability of the displayed information or improved workflow management.

Note 3 to entry: For devices intended to deliver a drug, the *clinical outcome* (3.10) relates to the precision and accuracy of drug delivery, enhance patient adherence and compliance, and improve disease management and control.

**3.11****clinical outcome parameter**

specified, measurable indicator used to assess the *clinical outcome* (3.10)

Note 1 to entry: The purpose of the *clinical outcome parameter* (3.11) is to objectively measure the intended *clinical benefit* (3.3)(s) to the patients, and where relevant, to users and public health. The *evaluation criteria* (3.18) for the *clinical outcome parameter* (3.11) can be derived from the relevant standards and medical consensus guidelines in patient care or other sources of *available knowledge* (3.2).

**3.12****clinical performance**

ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its *intended purpose* (3.22) as claimed by the manufacturer, thereby leading to a *clinical benefit* (3.3) for patients, when used as intended by the manufacturer

**3.13****clinical risk**

combination of the probability of occurrence of harm and the severity of that harm to health of people resulting from the medical device, when the device is used as intended for its medical purpose

Note 1 to entry: Harm to the health of people in the context of the *clinical evaluation* (3.7) is only relevant, if the harm is directly associated with the *clinical use* (3.14) of the device.

**3.14****clinical use**

use of a medical device on humans for treatment, diagnosis or patient management purposes

**3.15****clinically relevant claim**

direct or indirect assertion made by the manufacturer pertaining to the *safety* (3.24), *clinical performance* (3.12) or *effectiveness* (3.17) including *clinical benefit* (3.3)(s) of a medical device when used as intended

Note 1 to entry: Claims are commonly made in the instructions for use, promotional material(s), websites or other media controlled by the manufacturer.

**3.16****digital evidence**

results of computational modelling and simulation or artificial intelligence (AI)-based analysis, used as part of an evaluation provided in a prescribed format that encompass in silico trials in silico tests and synthetic *clinical data* (3.5)

Note 1 to entry: *Digital evidence* (3.16) is also known as in silico evidence and can be derived from clinical and non-clinical data.

[SOURCE: Modified from Avicenna Alliance (2023), Avicenna Alliance Glossary Terms for Computer Modelling and simulation (3rd ed.) [2]]

### 3.17

#### **effectiveness**

ability of a medical device to achieve clinically meaningful outcome(s) in its *Intended use* (3.22) as claimed by the manufacturer

[SOURCE: IMDRF MDCE WG/N56final:2019; clinical evaluation<sup>[1]</sup>]

### 3.18

#### **evaluation criteria**

set of predetermined reference conditions that serve as a basis for evaluation or comparison to demonstrate that the expected *clinical outcome parameters* (3.11) are met

Note 1 to entry: Determined based on outcomes achievable with other *state of the art* (3.28) and *standard of care* (3.27), therapeutic or non-therapeutic alternatives (including diagnostic options), with the same *intended use* (3.22) or patient population. *evaluation criteria* (3.18) can be derived from product specific standards or medical consensus guidelines.

Note 2 to entry: *Evaluation criteria* (3.18) for specific clinical outcomes are measurable and preferably quantitative, but may be expressed as a range with confidence intervals, where applicable.

### 3.19

#### **expected lifetime**

time period specified by the manufacturer during which the medical device or accessory is expected to remain safe and effective for use

Note 1 to entry: The *expected lifetime* (3.19) can be affected by the stability.

Note 2 to entry: Maintenance, repairs or upgrades (e.g. *safety* (3.24) or cybersecurity modifications) can be necessary during the *expected lifetime* (3.19).

Note 3 to entry: Some medical devices have an absolute lifetime (e.g. 5 y), whereas other medical devices (e.g. software) have a relative lifetime (e.g. the time between two major releases).

[SOURCE: ISO 20417:2021, 3.7 – modified by deleting Note 4 to entry]

### 3.20

#### **life cycle**

series of all phases in the life of a medical device (3.10), from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:2019,<sup>[4]</sup> 3.5]

### 3.21

#### **information provided to the user**

information provided by the manufacturer on the label, in the instructions for use or in promotional, training or sales materials or statements accessible (oral or written) to the user

### 3.22

#### **intended use**

intended purpose

use for which a medical device is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: *Intended use* (3.22) can include indications for use.

### 3.23

#### **performance**

ability of a medical device to achieve its *intended purpose* (3.22) as stated by the manufacturer

Note 1 to entry: *Performance* (3.23) may include both clinical and technical aspects.

[SOURCE: IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2)<sup>[5]</sup>]

**3.24****safety**

freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 63:2019,<sup>[4]</sup> 3.10]

**3.25****similar device**

medical devices that share the same or similar *intended use* (3.22), technology or principle of operation but can differ in specific design or materials

Note 1 to entry: The word 'similar' in this document does not have any regulatory connotation, but refers to devices that can provide relevant clinical or technical data to support *clinical evaluation* (3.7), with adequate justification.

**3.26****simulated use**

non-clinical evaluation of a medical device's *performance* (3.23), usability, and *safety* (3.24) by replicating intended clinical scenarios using artificial models, virtual environments, or simulated physiological conditions, without involving actual patients or human subject

**3.27****standard of care**

treatment or diagnosis that experts agree is appropriate, accepted, and widely used for a given disease or *clinical condition* (3.4)

Note 1 to entry: *Standard of care* (3.27) can vary from one geographic region to another.

**3.28****state of the art**

developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The *state of the art* (3.28) embodies what is currently and generally accepted as good practice in technology and medicine. The *state of the art* (3.28) does not necessarily imply the most technologically advanced solution. The *state of the art* (3.28) described here is sometimes referred to as the "generally acknowledged *state of the art* (3.28)".

Note 2 to entry: *State of the art* (3.28) is a subset of *available knowledge* (3.2).

[SOURCE: IMDRF GRRP WG/N47 FINAL:2024<sup>[5]</sup> modified by adding Note to Entry 2]

## 4 Symbols and Abbreviations

|      |                               |
|------|-------------------------------|
| AI   | Artificial Intelligence       |
| DUE  | Device Under Evaluation       |
| IFU  | Instructions for Use          |
| QMS  | Quality Management System     |
| RWD  | Real World Data               |
| SOTA | State of the Art              |
| WET  | Well Established Technologies |

## 5 General requirements

### 5.1 Purpose of the clinical evaluation

The purpose of clinical evaluation is to assess safety and clinical performance or effectiveness including clinical benefit(s), and acceptability of the benefit-risk profile of the DUE. This ensures that patients, healthcare providers and other users have access to effective medical devices and are safeguarded from potential unacceptable risks associated with their use.

The objective of clinical evaluation is to determine whether the DUE meets specified requirements for safety, clinical performance or effectiveness including clinical benefit(s) and the benefit-risk profile within its life cycle. These requirements shall be specified in relation to medical or non-medical alternatives for the same patient population and indications or intended use, as applicable.

The clinical evaluation process is an iterative assessment, and its objectives are dependent on the stage of the medical device life cycle. For example, in early development, when clinical data are not yet available, the clinical evaluation will focus on the evaluation of other available medical and non-medical alternatives with the aim of determining safety and performance requirements, including, where applicable, relevant clinical outcome parameters and associated evaluation criteria.

In mid-development, the objective may shift to defining clinical evidence requirements. In late development of the medical device life cycle, clinical evaluation may be performed with the objective of determining if adequate clinical evidence exists to demonstrate that the identified evaluation criteria have been met.

In the post-market phase, the objectives shift to evaluation of real-world data and any impacts of the evolution of the available knowledge. Further information can be found in [Table E.1](#).

NOTE 1 It is the manufacturer's responsibility to identify medical or non-medical alternatives and, if applicable, the appropriate target patient population.

The clinical evaluation shall address, where applicable:

- a) all medical device models, variants and combinations;

NOTE 2 Clinical evidence from one model or combination can be used, if needed, provided adequate rationale and justification for transferability of data is documented.

- b) intended use, including all indications for use and specifics of intended patient populations, as applicable;
- c) intended user(s);
- d) conditions of use;
- e) risks identified through risk management and review of the available knowledge;
- f) risks and benefits identified from clinical and relevant non-clinical data;
- g) potential risks from misuse or off-label use;
- h) duration of use, including potential long-term impacts of medical devices intended to be used for a limited period of time;
- i) expected medical device lifetime
- j) use of the DUE in combination with other devices and products.

The clinical evaluation shall provide a basis to determine the need for additional clinical or other relevant data, including pre-or post-market data, as necessary.

NOTE 3 The clinical evaluation can serve as evidence of conformance with the relevant essential principles.

## 5.2 Management Responsibilities

The manufacturer is responsible for the clinical evaluation within the medical device life cycle. Top management shall demonstrate its commitment to the clinical evaluation by implementing and maintaining a clinical evaluation process, ensuring the provision of adequate resources and assigning competent personnel to conduct the clinical evaluation and related tasks.

The manufacturer shall ensure a clear and strong interaction between the processes of clinical evaluation, design and development, risk management, clinical development, regulatory strategy and post-market surveillance.

## 5.3 Clinical evaluation process

Clinical evaluation is an essential part of medical device design and development and is closely linked to the risk management process through the identification, analysis and assessment of clinical risks and benefits (see [Figure 1](#)). The manufacturer shall make a reasoned decision on the type and scope of the clinical evaluation. This decision depends on the type of medical device and the clinical risk potential.

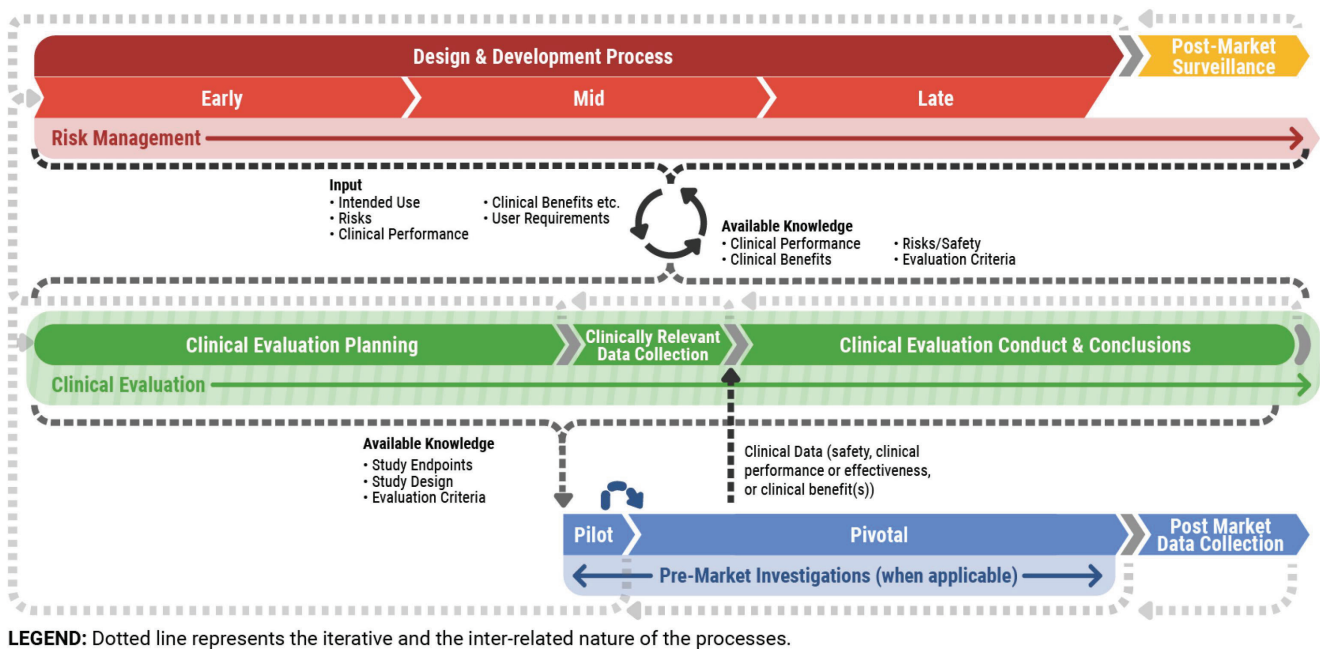


**Figure 1 — Clinical evaluation process interfaces**

The clinical evaluation process includes planning, collection, appraisal and analysis of clinical and non-clinical data relevant to a DUE using a methodologically sound procedure and coming to a conclusion and recommendation for further generation of pertinent data (see [Figure 2](#)).