Your
Regulatory
Partner

QAdvis Free Webinar
Usability Engineering
according to IEC 62366-1

QAdvis

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech manufacturers
Founding member of EAAR (European Association of Authorized Reps)

UK Responsible Person

Founding member of UKRP Association

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Doc
Global Regulatory Support
Clinical Evidence, Clinical evaluations
Vigilance, Recalls, Post market

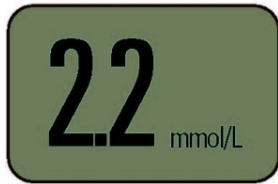# Presentation of the speaker – Cilla Lundevall

- Senior Quality and Regulatory Consultant @ QAdvis

- MSc EE & Medical Radiation physics

- 24 years in Medical Device Industry

- 20 years in Medical Device QA
  – V&V
  – QA/RA Consultant
  – PRRC, Head of QA/RA

Usability and Medical Devices

Some examples from UPAXA (The User Experience Professionals Association)

- Glucose meter recall – poor visibility decimal point

- Monitoring device recall - ineffective alarm system

- *"In 2008, the FDA recalled an ultrasound system because the graphics made users misunderstand the image orientations of the patient's left and right sides"*

Ref: http://uxpamagazine.org

Agenda

1. Regulations & Standards

2. Overview & Definitions

3. The Usability Engineering Process

4. Q&A

Regulatory Context

MDD
Medical Device Directive

AIMDD
Active Implantable Medical Device Directive

MDR
Medical Device Regulation

GSPR 5

IVDD
In Vitro Diagnostic Medical Device Directive

IVDR
In Vitro Diagnostic Medical Device Regulation

Regulations and Standards (EU)

EU Commission

National Laws

Legally binding

MDR   IVDR

GSPR 5

MDR = the Medical Device Regulation (Regulation 2017/745)
IVDR = the In Vitro Medical Device Regulation (Regulation 2017/746)

MDR / IVDR Requirements on Usability – GSPR 5

In eliminating or reducing risks related to use error, the manufacturer shall

Design for patient safety

Design for lay, professional, disabled or other users

Reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used

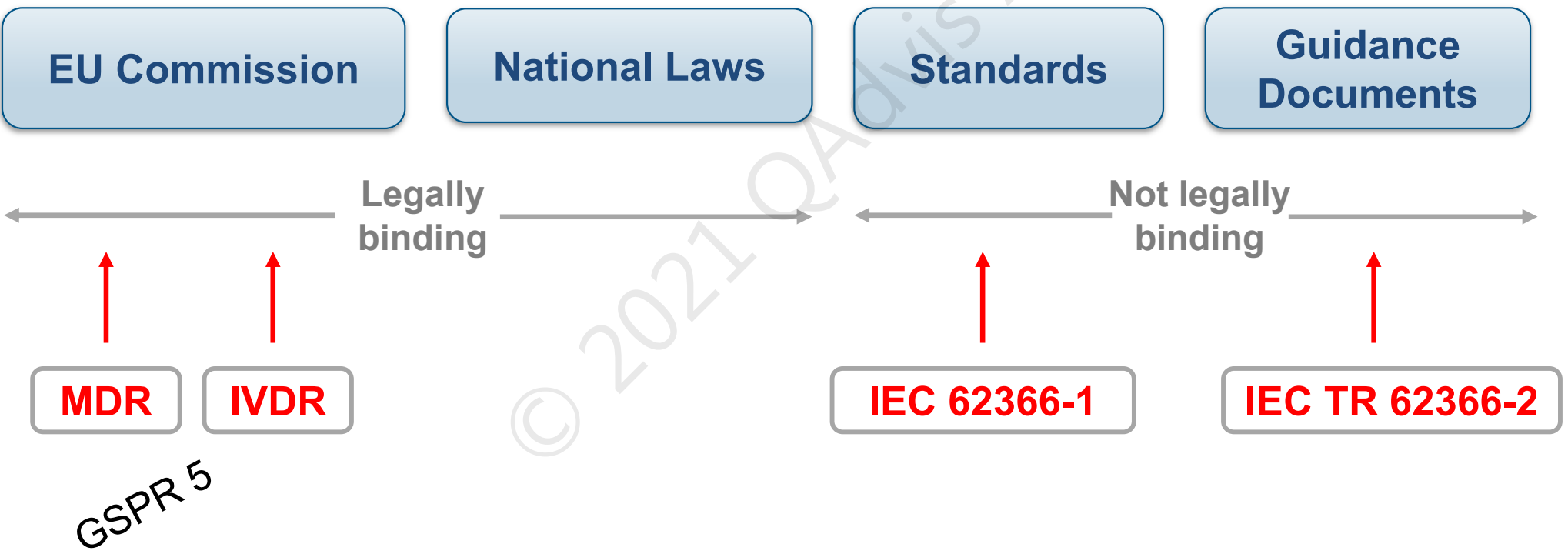technical knowledge

experience

education

training

medical and physical conditions

use environment

GSPR = General Safety and Performance Requirement

Regulations and Standards (EU)

EU Commission   National Laws   Standards   Guidance Documents

Legally binding   Not legally binding

MDR   **IVDR**   **IEC 62366-1**   **IEC TR 62366-2**

GSPR 5

MDR = the Medical Device Regulation (Regulation 2017/745)
IVDR = the In Vitro Medical Device Regulation (Regulation 2017/746)

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Usability

IEC 62366-1:2015/A1:2020
IEC TR 62366-2:2016

IEC 62366-1
Edition 1.0   2015-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices –
Part 1: Application of usability engineering to medical devices

IEC TR 62366-2
Edition 1.0   2016-04

TECHNICAL REPORT

Medical devices –
Part 2: Guidance on the application of usability engineering to medical devices

EUROPEAN STANDARD   **EN 62366-1:2015/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM   August 2020

OVERVIEW OF 62366-1
& DEFINITIONS

Your
Regulatory
Partner

Focus on Safety

Safety *or* **Safety**
+
Other aspects
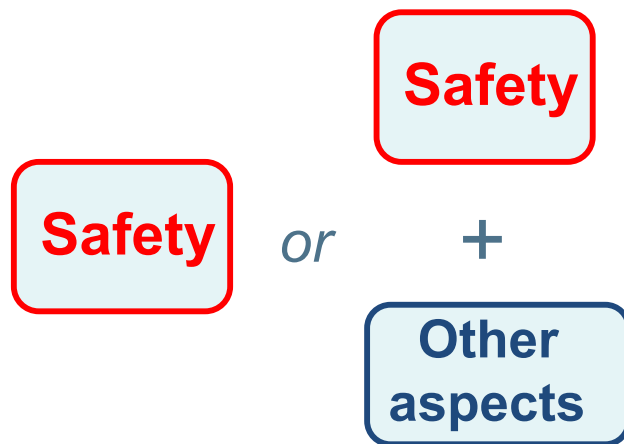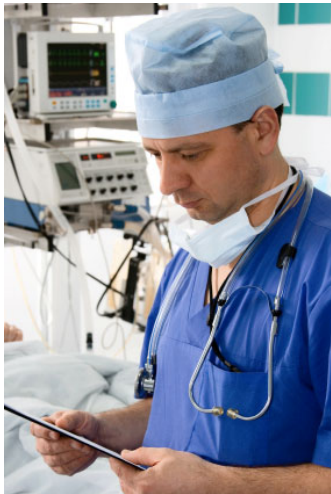
*Manufacturers can choose to implement a usability engineering program focused narrowly on **safety** or more broadly on **safety and other attributes***

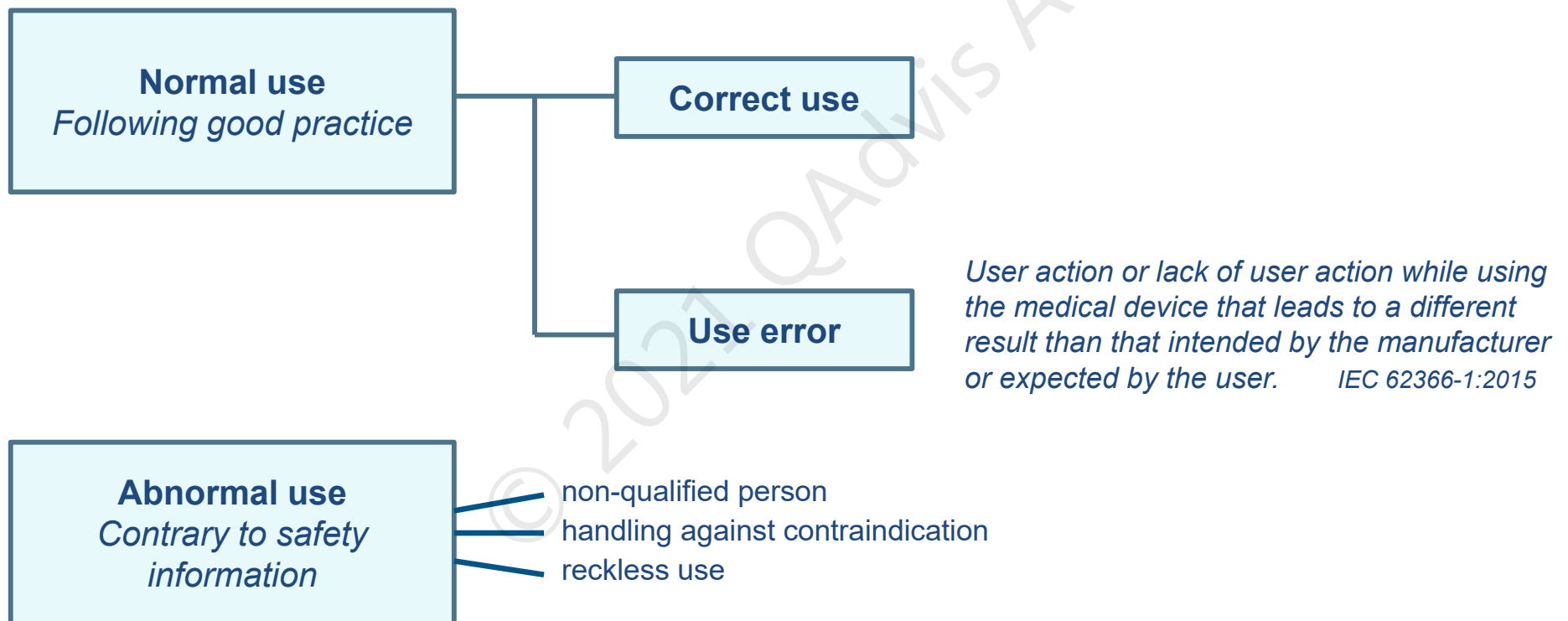IEC 62366-1:2015

Definitions – User - Usability

User Person **interacting with** the medical device

E.g. nurses, physicians, laboratory technicians, patients, service personnel

Usability Characteristic of the user interface that **facilitates use** and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment
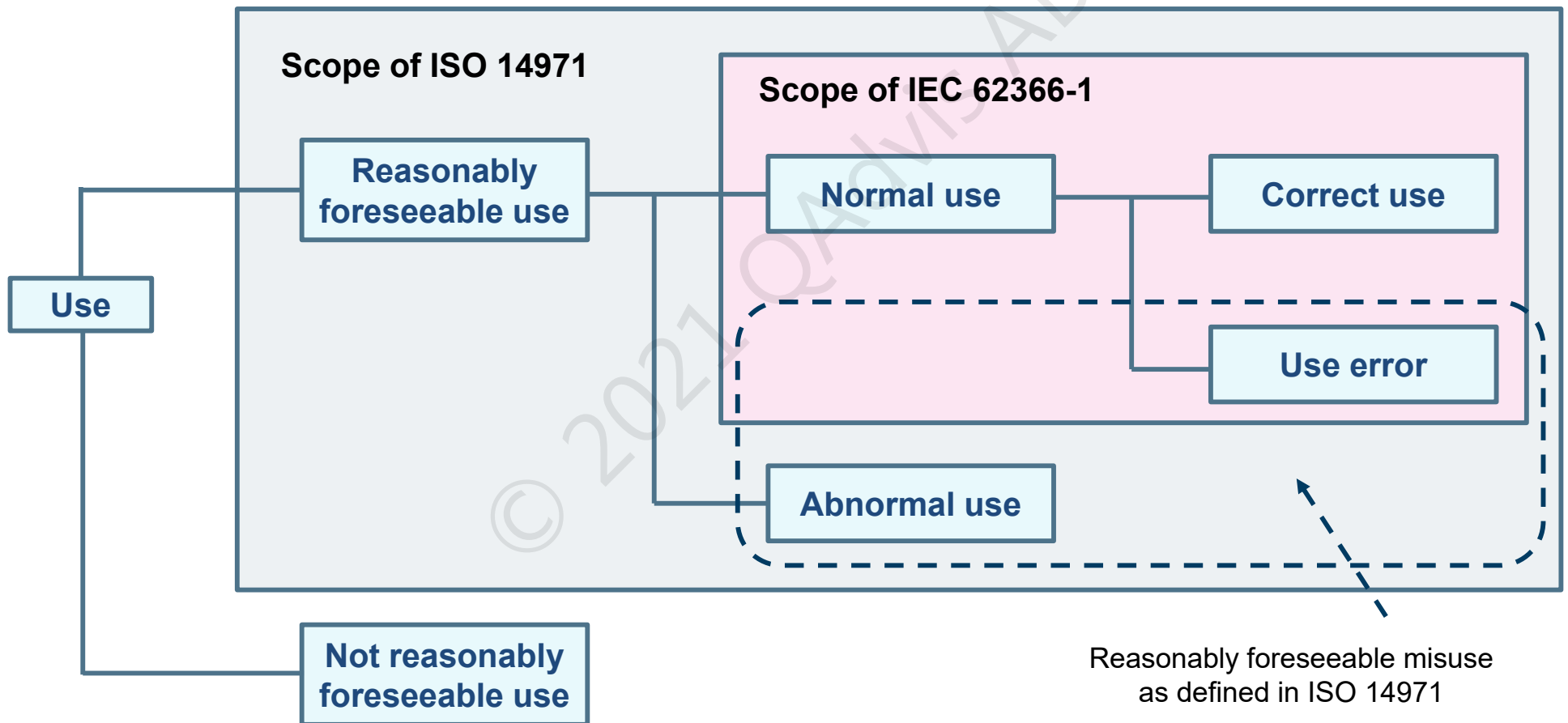
effectiveness = *accuracy and completeness with which users achieve specified goals*
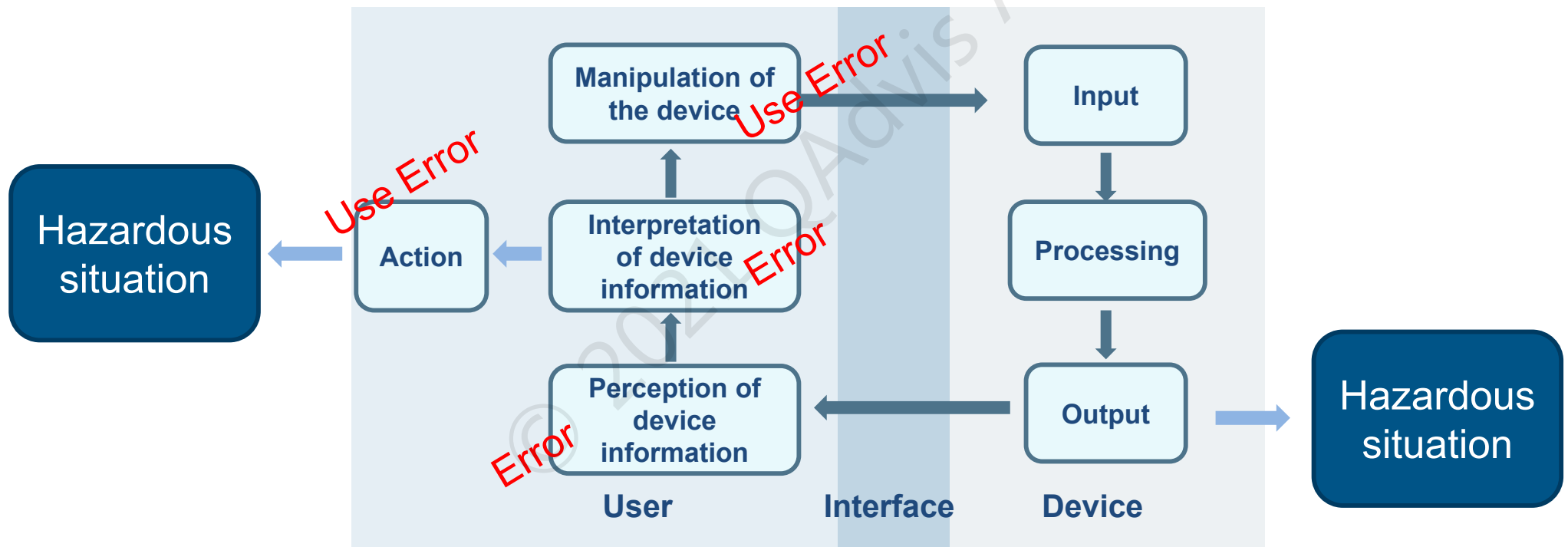efficiency   = *resources expended in relation to effectiveness*

IEC 62366-1:2015

Definitions – normal/abnormal use, use error

Scope of ISO 14971

Scope of IEC 62366-1

Use

Reasonably foreseeable use

Normal use

Correct use

Use error

Abnormal use

Not reasonably foreseeable use

Reasonably foreseeable misuse as defined in ISO 14971

Hazardous situations

User Interface of Unknown Provenance (UOUP)

User interface or part of user interface of a medical device previously developed for which adequate records of the usability engineering process of this standard are not available

IEC 62366-1:2015

THE USABILITY ENGINEERING PROCESS

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The Usability Engineering Process – General

- The manufacturer shall **establish**, **document** and **maintain** a *Usability Engineering Process* to provide **safety** for the patient, users and others

- The process shall address **user interactions** with the medical device according to the accompanying document, including, but not limited to:
    - **Transport**
    - **Storage**
    - **Installation**
    - **Operation**
    - **Maintenance & repair**
    - **Disposal**

IEC 62366-1:2015

Tailoring of the Usability Engineering Process
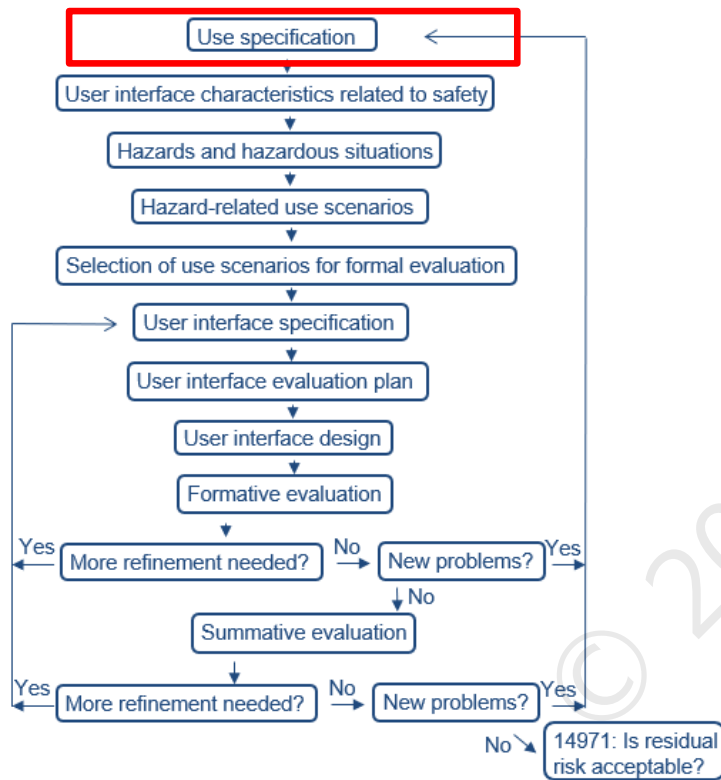
The Usability Engineering Process - Components
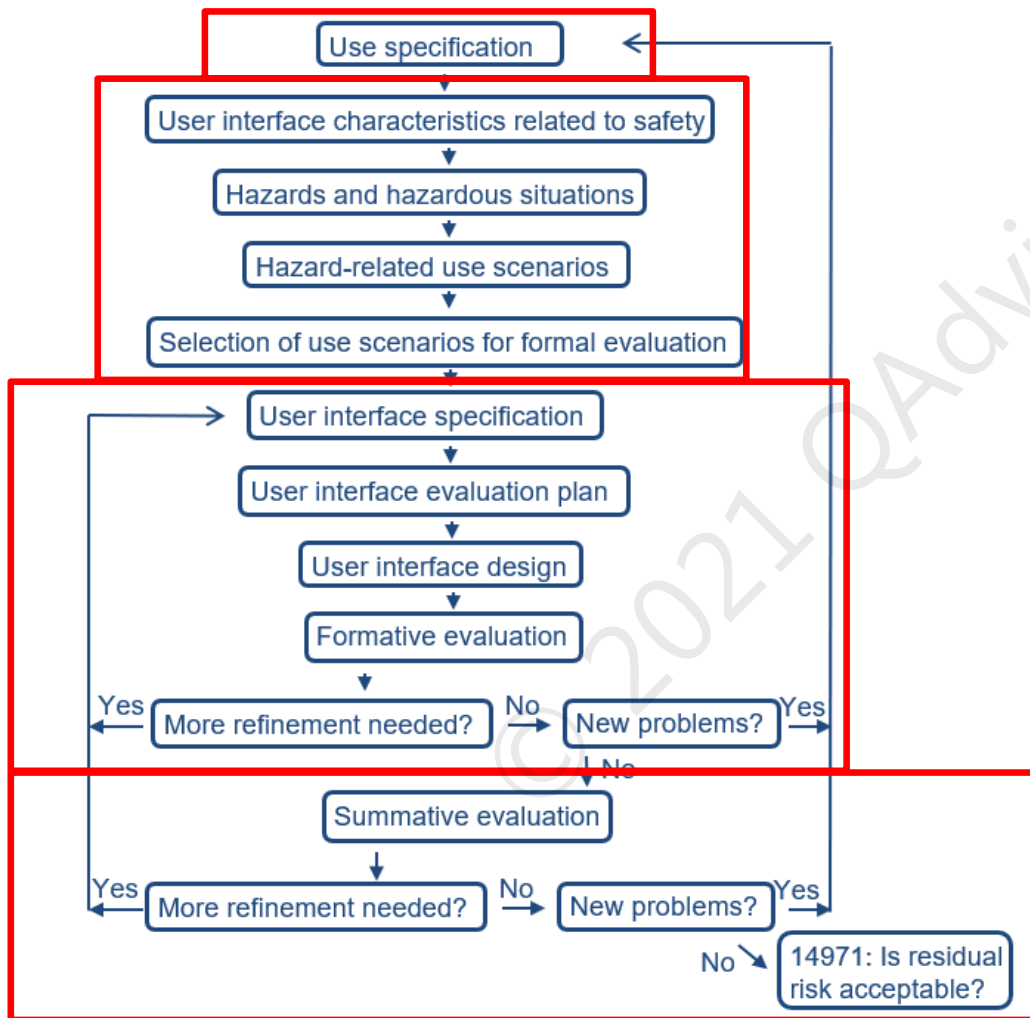
The Usability Engineering Process - Input

1.	**Use specification**

The Usability Engineering Process - Risk
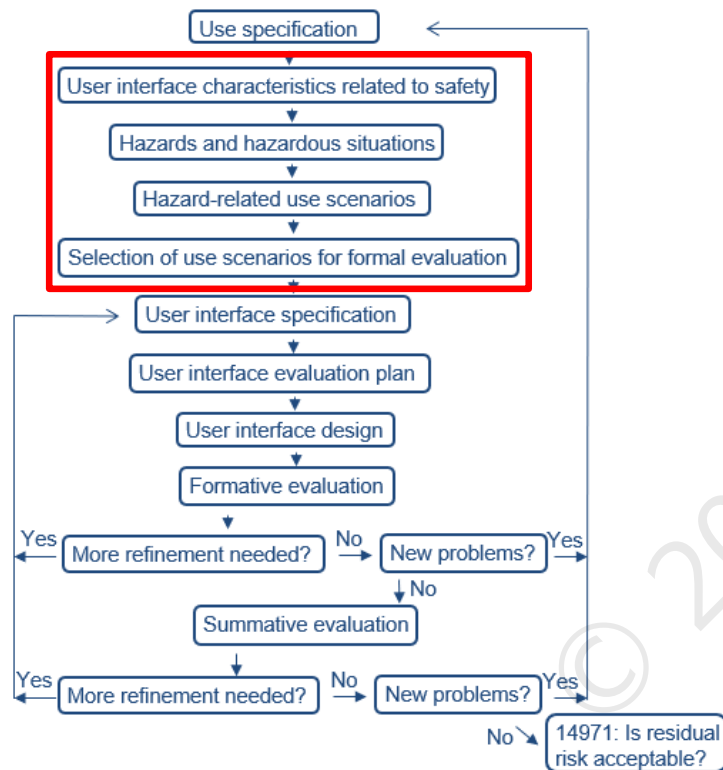
|	
1.	Use specification
2.	**User interface characteristics related to safety and potential use errors**
3.	**Known or foreseeable hazards and hazardous situations**
4.	**Hazard-related use scenarios + selection for summative testing**

Usability – Closely Related to Risk Management Process
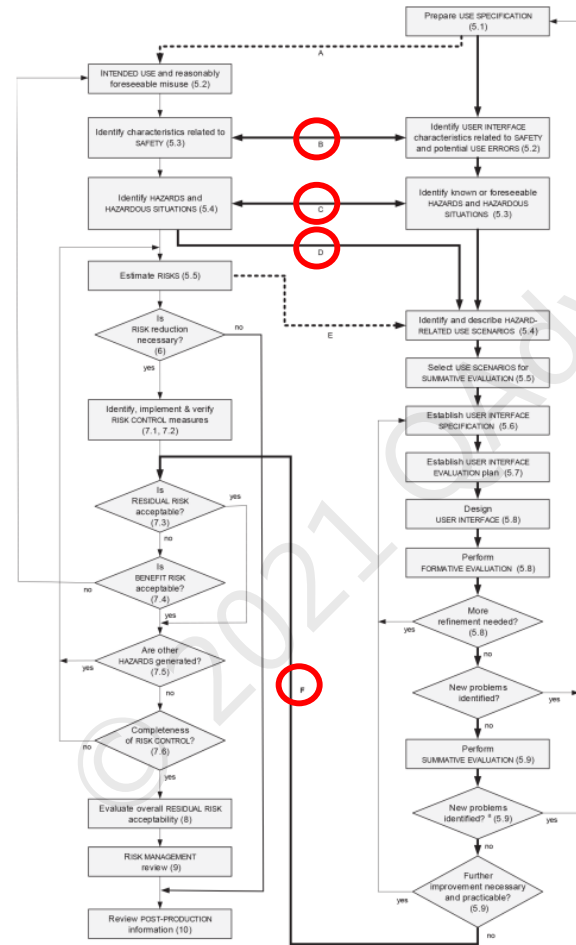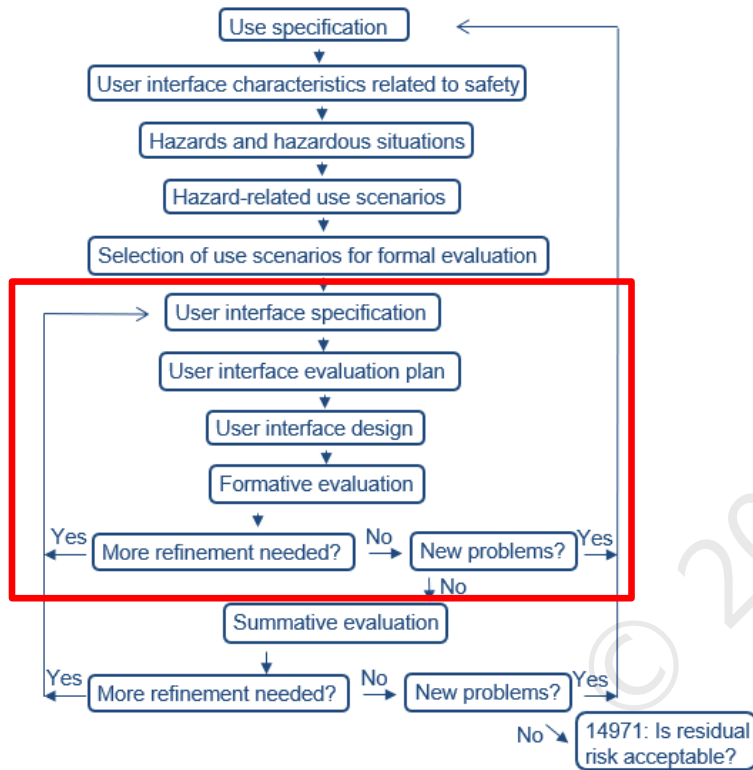

14971:2019   *62366-1:2015/A2:2020*

User Interface Characteristics Related to Safety and Potential Use Errors

```
┌─────────────────────────┐         ┌──────────────────────────────┐
│  Identify characteristics│  ←────→ │   Identify user interface     │
│  related to safety       │         │ characteristics related to safety│
│                          │         │   and potential use errors    │
└─────────────────────────┘         └──────────────────────────────┘
        14971:2019                      62366-1:2015 /A1:2020
```
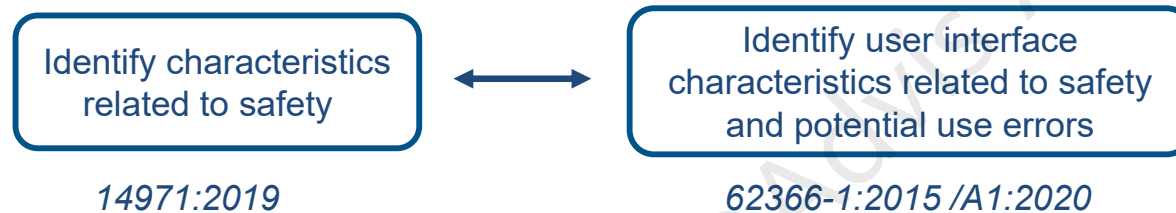
Input

- Annex A ISO/TR 24971:2020. Questions for identification of hazards and medical device characteristics related to safety. Includes usability-related aspects.

- Experience from previous products (customer complaints, incidents, literature)

- Task analysis - a tool to identify potential use errors (IEC TR 62366-2:2016, 9.1)

The Usability Engineering Process – Design & Development

1.	Use specification
2.	User interface characteristics related to safety and potential use errors
3.	Known or foreseeable hazards and hazardous situations
4.	Hazard-related use scenarios + selection for summative testing
5.	**User interface specification**
6.	**User interface evaluation plan (formative and summative evaluations)**
7.	**User interface design incl. formative evaluation**

User interface evaluation plan
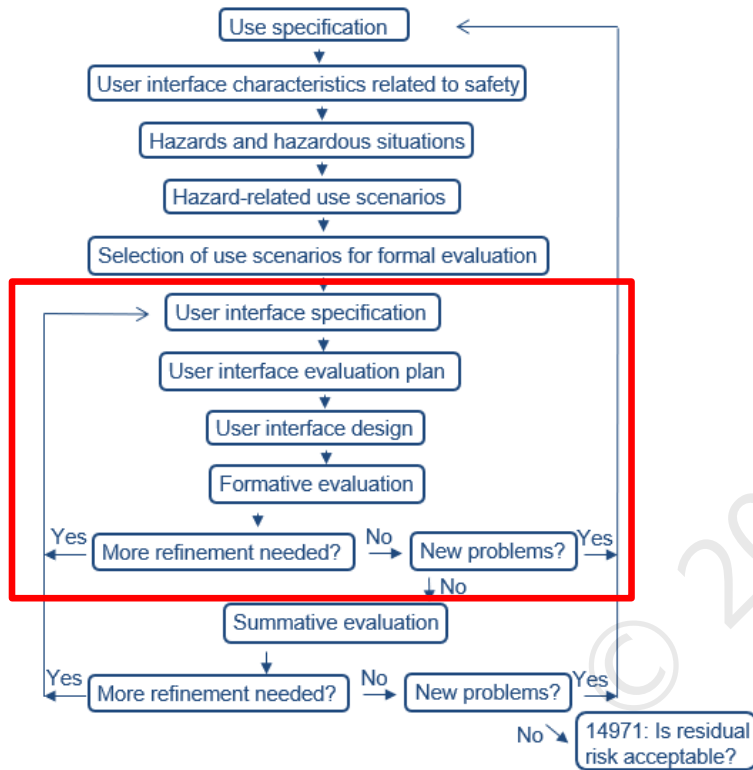# Formative vs Summative Usability Testing

Formative usability testing

- Iteratively performed during product development
- Advisory testing using sketches, prototypes etc.
- Input to interface concepts and design (strengths, weaknesses, use errors)
- No formal acceptance criteria
- *"Good usability engineering practice suggests conducting at least one formative evaluation ahead of a summative evaluation."* IEC 62366-2:2016

Summative usability testing

- Performed at the end of product development
- Final product (or equivalent)

- Validation of the safe use of the user interface, including information for safety
- Formal acceptance criteria

The Usability Engineering Process – Design & Development

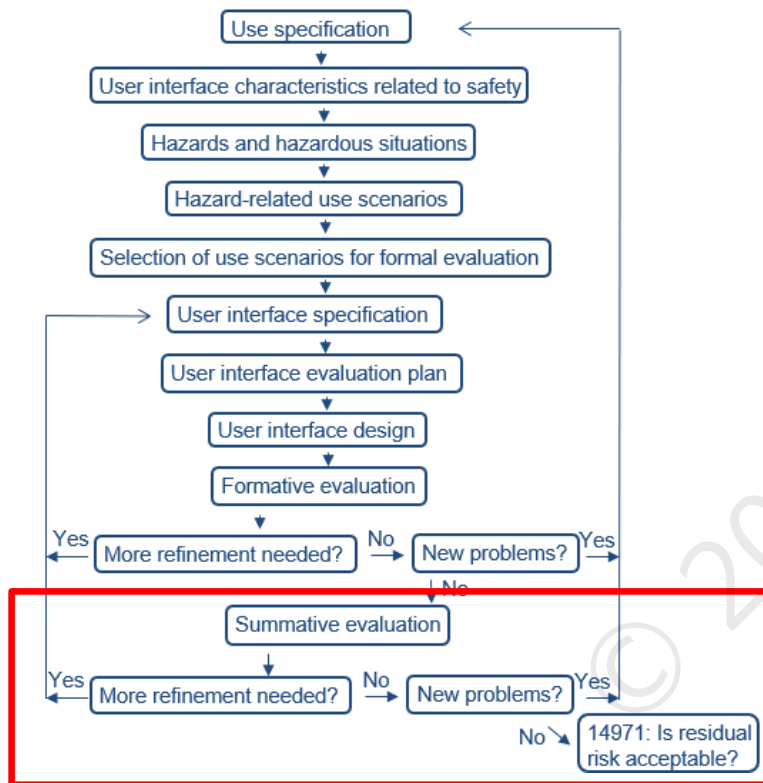|	
1.	Use specification
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5.	**User interface specification**
6.	**User interface evaluation plan (formative and summative evaluations)**
7.	**User interface design incl. formative evaluation**

User Interface Design and Implementation

- Includes **formative testing** & **iterative design** and implementation

- **Accompanying documentation**

- **Training materials**
  (if training is necessary for the safe use of the device)

- **Multidisciplinary team**

    Suggested competences (part 1, 5.8): *users, engineers, user-interface specialists, cognitive psychologists, multimedia programmers, usability engineers, marketing and training personnel*

    Guidance on design and implementation of user interface is available in IEC 62366-2:2016, chapter 15

The Usability Engineering Process – validate and evaluate

1.	Use specification
2.	User interface characteristics related to safety and potential use errors
3.	Known or foreseeable hazards and hazardous situations
4.	Hazard-related use scenarios + selection for summative testing
5.	User interface specification
6.	User interface evaluation plan (formative and summative evaluations)
7.	User interface design incl. formative evaluation
8.	**Summative evaluation**

Next steps

- Read the standard & guidance

- Focus on risks

- Further training
  January 18 2022, 4h online training

- Additional support
  https://www.qadvis.com/our-services/

www.qadvis.com