COMBINATION PRODUCTS SUMMIT

COLUMBUS, OH • NOVEMBER 7–9, 2022

Integrating Human Factors into Your Next Regulatory Submission

Shannon Clark
Founder & Principal
UserWise, LLC
Userwise@userwiseconsulting.com

Shannon Hoste
President
Agilis Consulting Group
Shoste@Agilisconsulting.com

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

AFDO RAPS

Shannon Clark

Founder & Principal

Licensing: Certified Professional Industrial Engineer

Education: BS Mechanical Engineering and a technical breadth in Technology Management

Experience: Shannon E. Clark is the founder and Principal of UserWise, a consultancy that helps medical device manufacturers and start-ups to design safe and easy-to-use medical devices. The consultants at UserWise conduct usability testing for a variety of medical devices ranging from surgical robots to home-use injection platforms. UserWise consultants also perform safety assessments to comply with U.S. and international regulations related to Human Factors. Before founding UserWise in 2014, Shannon was a Human Factors Engineer at Intuitive Surgical and Abbott Laboratories.

Shannon graduated from UCLA with a B.S. in Mechanical Engineering and a technical breadth in Technology Management. Shannon is additionally a Certified Professional Industrial Engineer, holds two patents, and has written and published three books.

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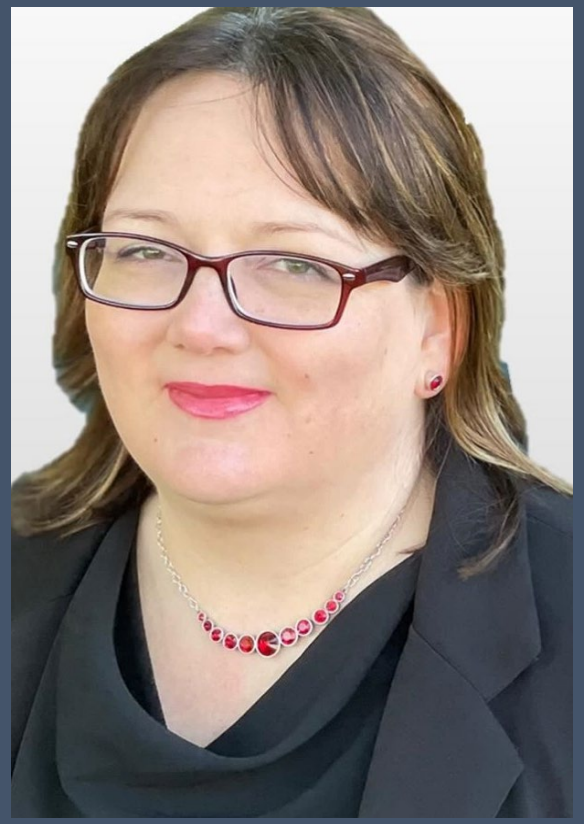

Shannon Hoste

President, Agilis Consulting
Associate Professor, Pathway for Patient Health

Education: BS Mechanical Engineering, MS Cognitive Systems Engineering, MS Management

Experience: President of Agilis Consulting Group, an associate professor in the Quality Science Education program at Pathway for Patient Health and is active on several standards and conference committees for medical devices and combination products.

Formerly, worked as Team Lead for Human Factors in FDA's Center for Devices and Radiological Health (CDRH) and as HF reviewer within the Center for Drug Evaluation and Research (CDER).

Additionally, she has 20+ years in industry where she has worked within and directed project teams in all phases of product development; as well as architecting process improvements for design controls, risk management, requirements management, software validation, system verification/validation and the incorporation of human factors and usability into overall product development processes.

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Overview

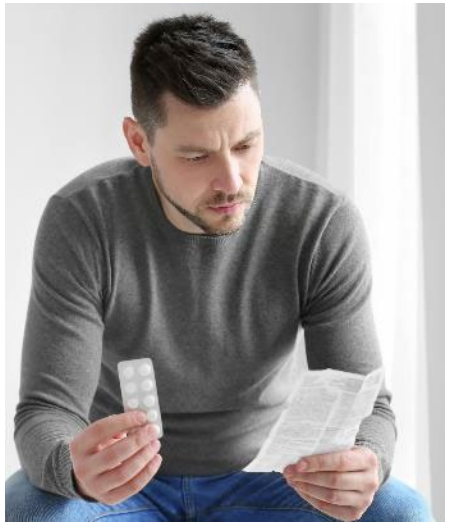
- Simulated use testing
- Alternative Summative Evaluation Techniques Accepted by the FDA
  - Standard Practice Arguments
  - Threshold Analysis/Comparison Arguments

What information does Summative Evaluation data provide?

What is human factors/usability engineering

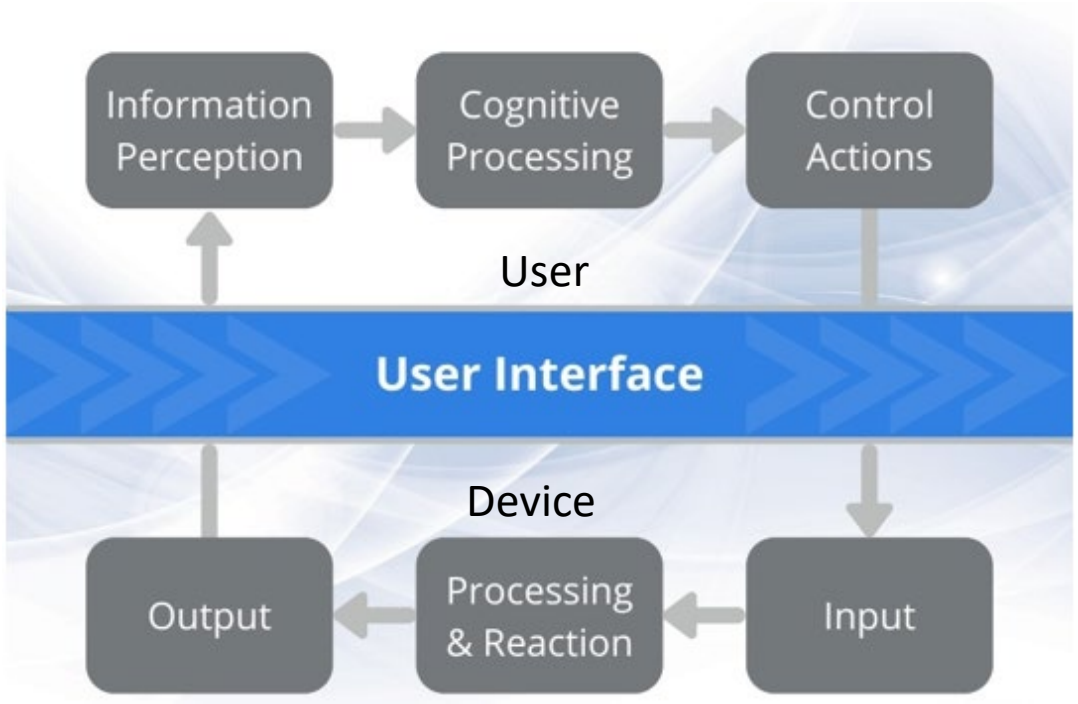
- Applying knowledge about human behavior, abilities, limitations, and other characteristics to the design of devices, systems, and tasks to improve usability

- Goal: optimize the user interface by minimizing use related hazards to ensure safe & effective use



What is human factors/usability engineering?

Human factors/usability engineering focuses on the **interactions** between people and user interfaces.



The design of the USER INTERFACE to achieve adequate USABILITY requires a different PROCESS and skill set than that of the technical implementation of the USER INTERFACE.
(From IEC 62366-1:2015/AMD-1:2020)

What is the user interface of a medical device/system?



All device/system components (including labeling) the user interacts with to transport, store, install, operate, maintain, repair and dispose of the device/system.

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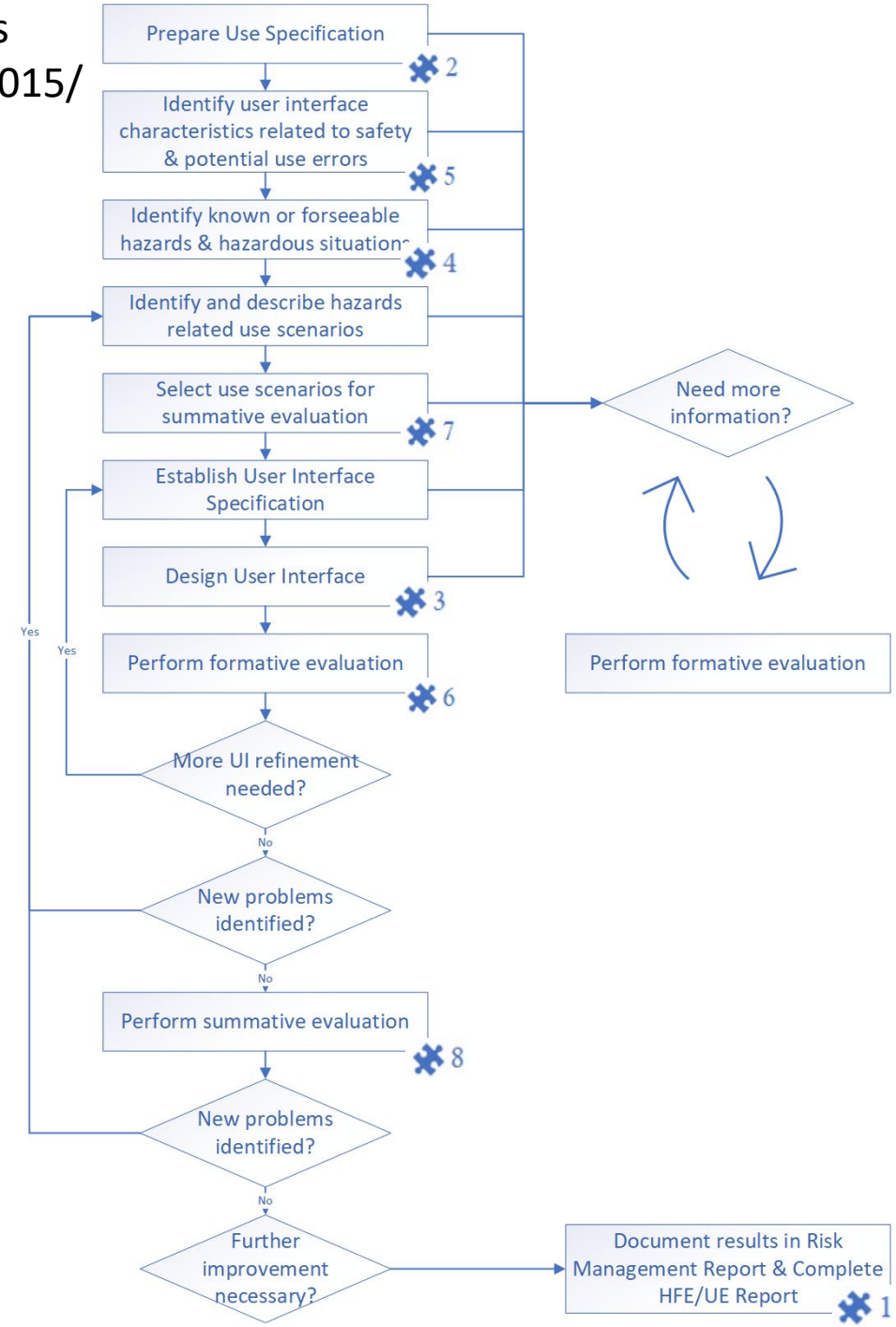
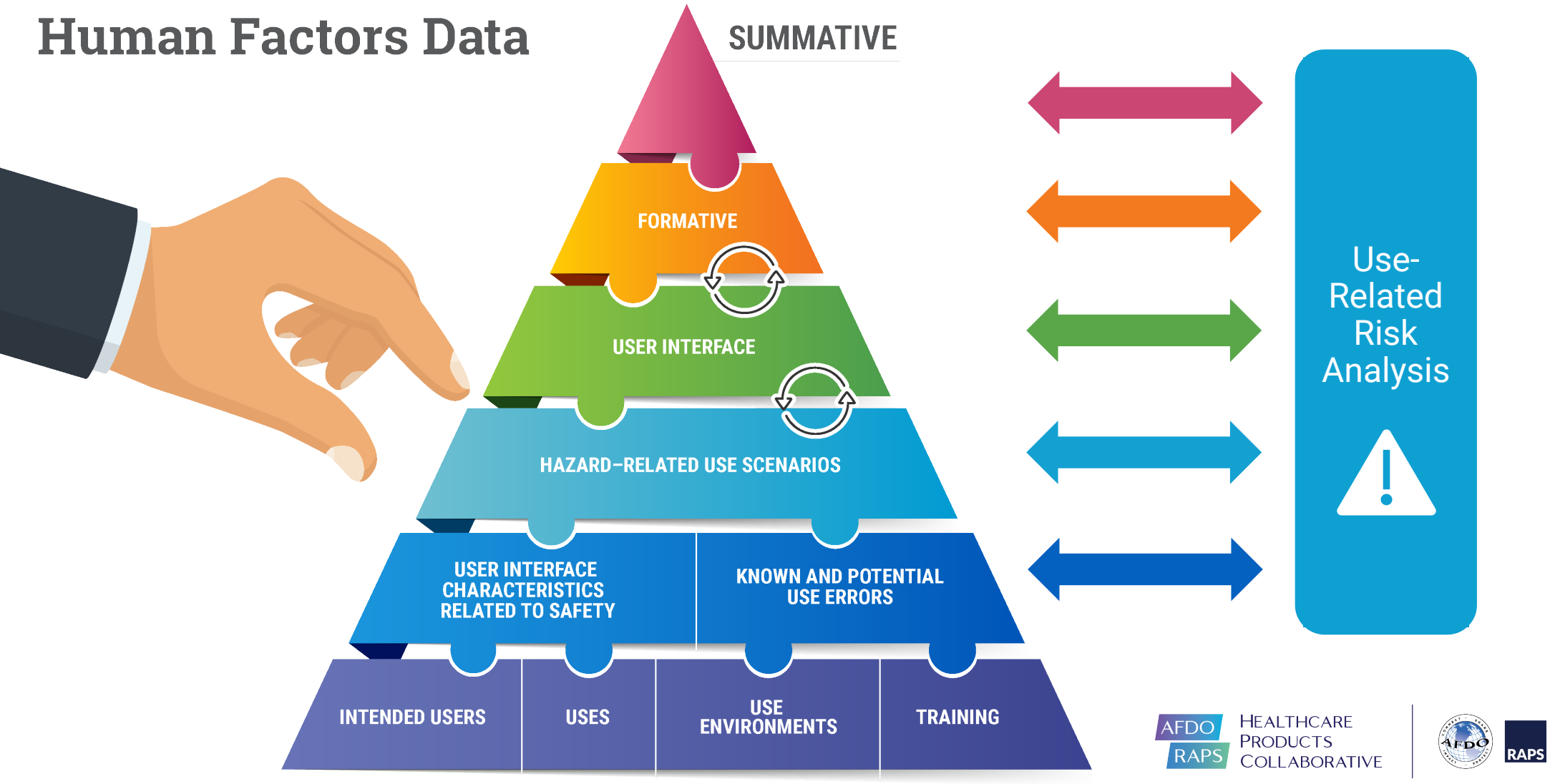
FDA Applying Human Factors and Usability Engineering to Medical Devices Table A-1 HFE/UE report

- 1 Conclusion
- 2 Description of intended device users, uses, use environments, and training
- 3 Description of device user interface
- 4 Summary of known use problems
- 5 Analysis of hazards and risks associated with use of the device
- 6 Summary of preliminary analyses and evaluations
- 7 Description and categorization of critical tasks
- 8 Details of human factors validation testing

HF/UE Process
IEC 62366-1:2015/
AMD-1:2020



Human Factors Data



Case studies

RISK: Critical tasks that should be considered are not.

- Post-market software upgrade.
- Validation study did not include critical tasks performed by technicians.
- During review of HFE/UE report, FDA CDRH requested additional human factors data.

→ 10-month delay to conduct supplemental validation and second FDA review

RISK: Potential use scenarios of concern that are not being considered.

- New surgical device.
- FDA requested data from missing use scenario for reprocessing components.

→ 14-month delay of submission to revise preliminary analysis, use case, URRA, conduct formative and validation

RISK: Study lacks structure to provide representative use data that is generalizable to actual use.

- Initial validation study included all trained participants.
- During FDA review of HFE/UE report, CDER asked for human factors data for untrained participants because, “You indicated that the training will be ‘offered’ to the patient but there is no assurance that all patients are trained.”

→ 15-month delay to conduct formatives and repeat validation AND 21-month delay to market due to submission delays

Leveraging regulatory authority interactions

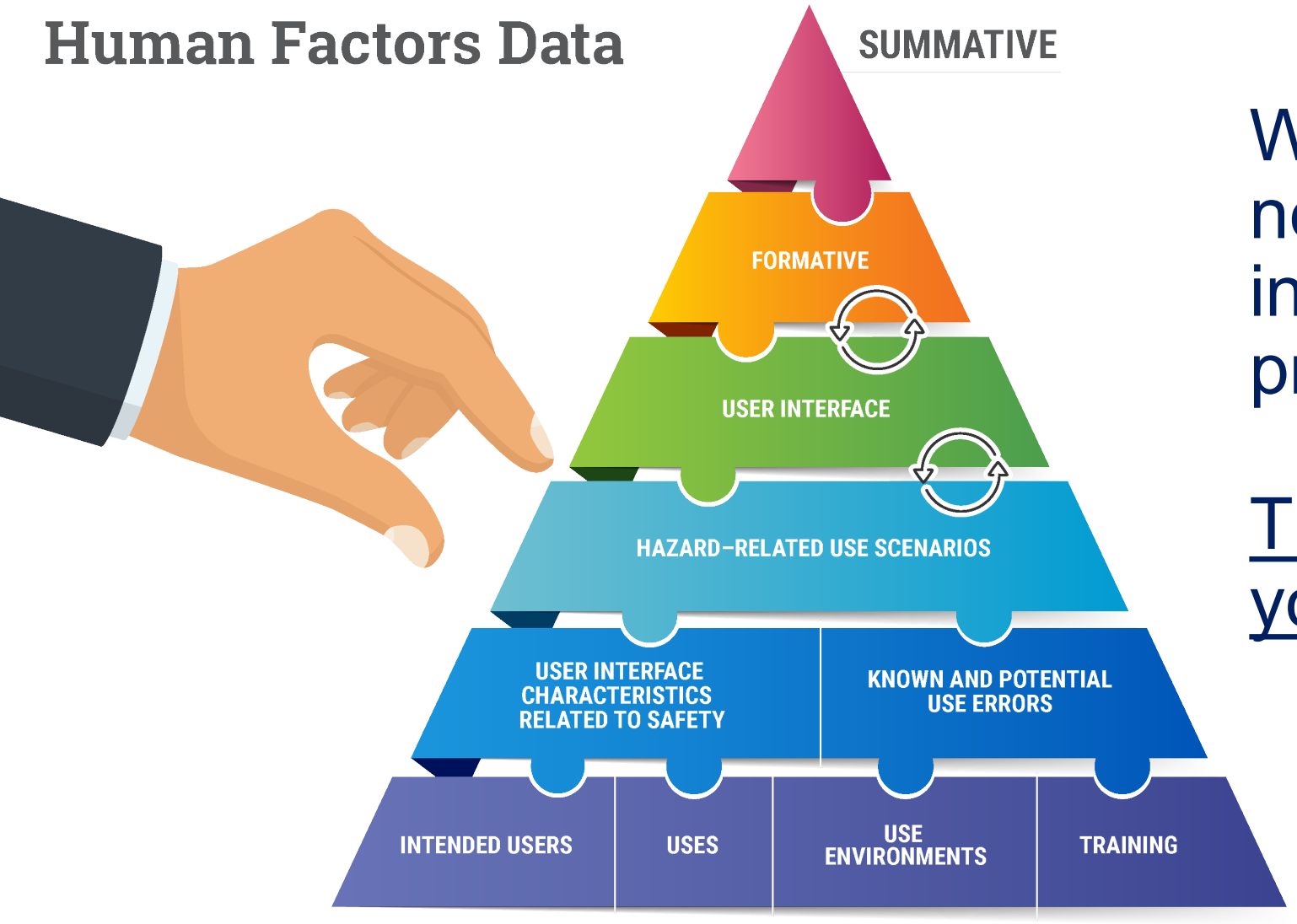
Goal to minimize:

- Risk to submission and regulator decision
- Need for additional work after the submission

Assess and seek alignment on:

- Device classification and/or submission type
- Pre-clinical strategy (if combination product)
- Questions related to human factors strategy
- Use-related Risk Analysis
- Human factors summative/validation protocol
- Labeling review for combination products

Human Factors Data

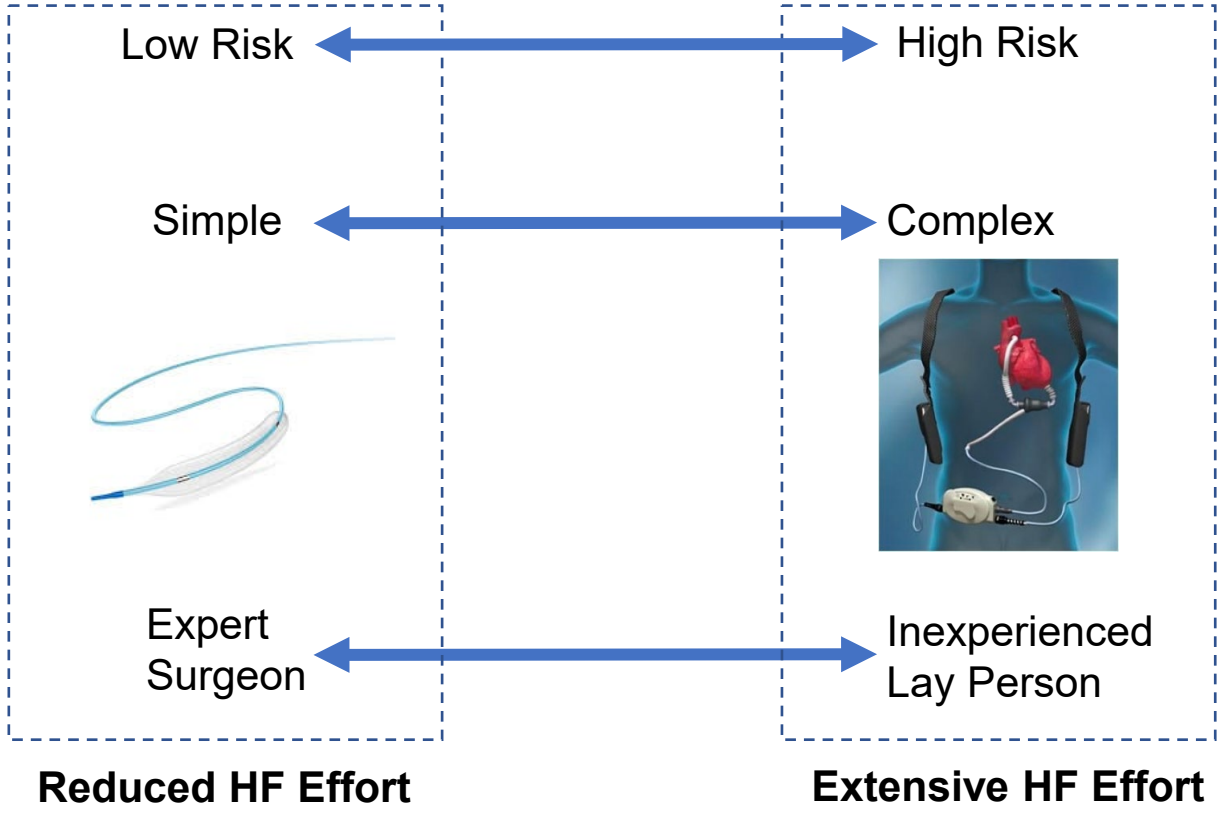


What summative data is needed is based on your intended use and your product user interface…

<u>This scales based on your use-related risk.</u>

Tailor Human Factors Effort According to...

- Device Complexity
- User Expertise



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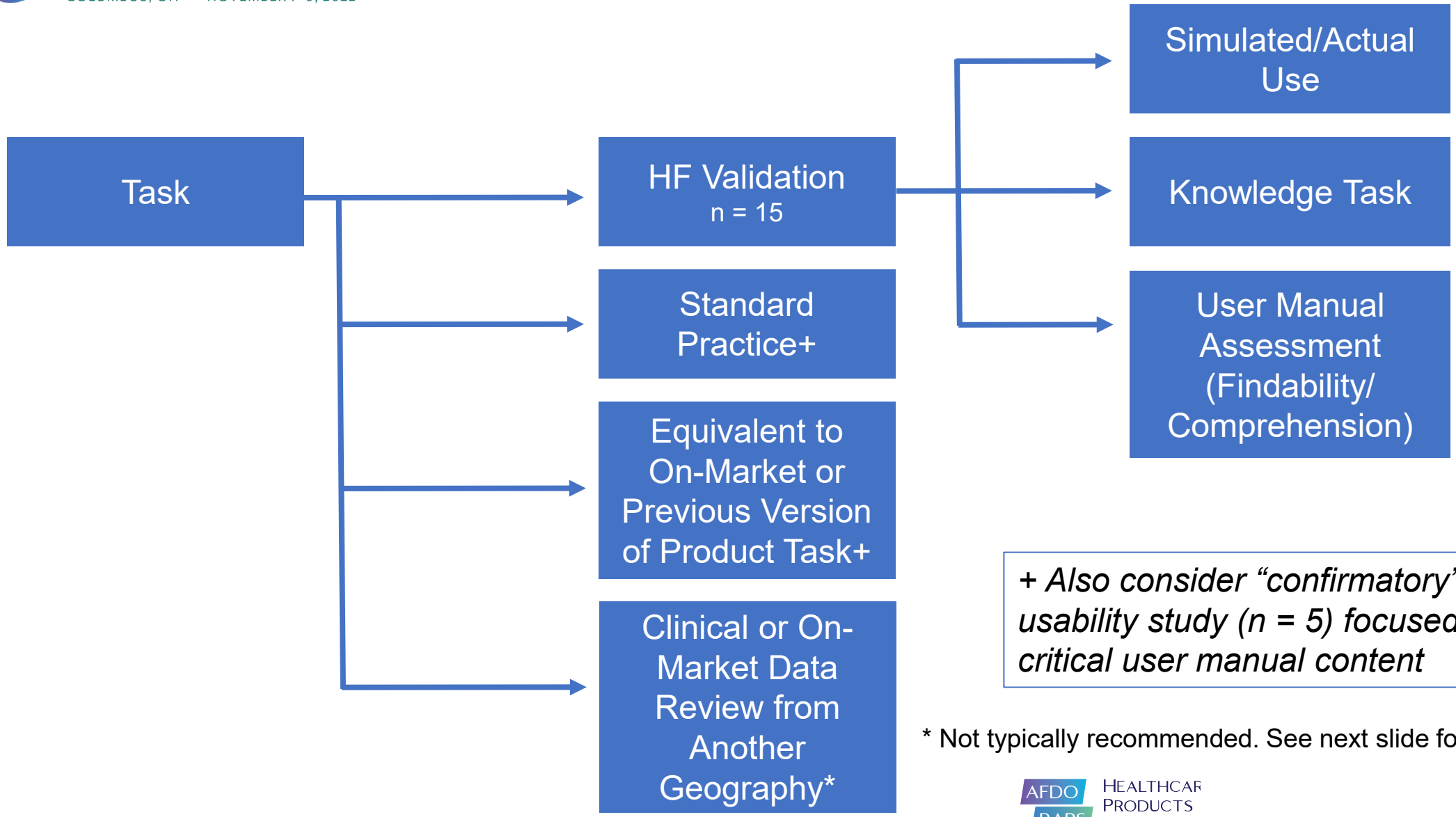
Summative Evaluation Techniques Accepted by the FDA

(This can also be used for compliance to IEC 62366-1)



+ Also consider "confirmatory" usability study (n = 5) focused on critical user manual content

* Not typically recommended. See next slide for further details

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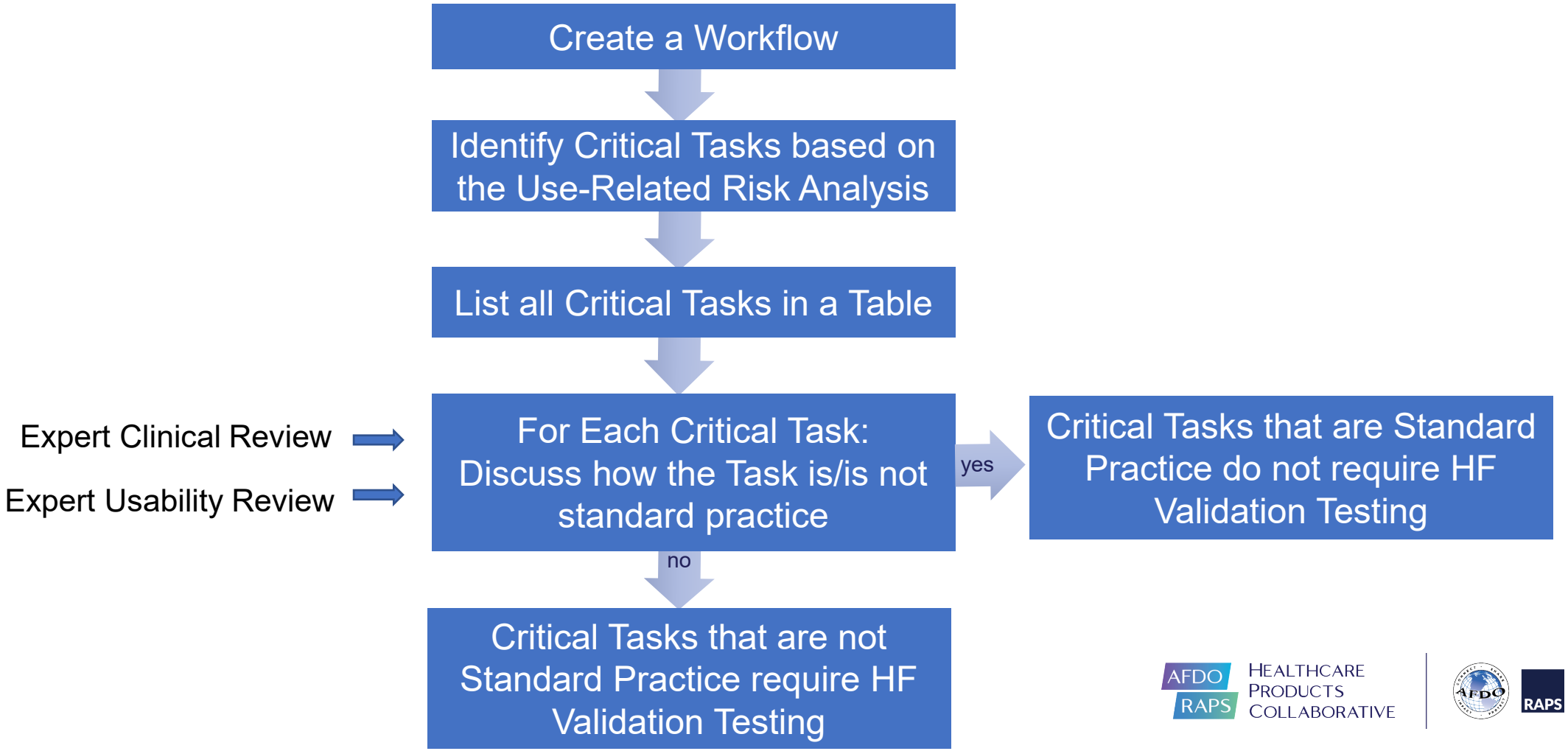
Standard Practice Justification

Summative Evaluation: Standard Practice Task



What is Standard Practice?

Our Definition:

A task which is considered "standard of care" (i.e., is standard across procedures conducted with various devices of similar indications for use) and which has a performance informed by the user's educational background and, in certain cases, in-service training (i.e., outside of the scope of the device user interface design).

Summative Evaluation: Standard Practice Task Assessment

- A robotic surgical system used with instruments and an electrosurgical unit

Example product image for illustration purposes only, from Intuitive Surgical Website.

Summative Evaluation: Standard Practice Task Assessment

Example:

- Task: Ensure sutures are adequate
- Assessment:
- Standard Practice:

What do you think?

Example product image for illustration purposes only, from Intuitive Surgical Website.

Summative Evaluation: Standard Practice Task Assessment

Example:

- Task: Ensure sutures are adequate
- Assessment: Task not unique to the system. Placing sutures is taught during surgical training (medical school / residency / fellowship).
- Standard Practice: Yes

No need to assess in HF Summative Validation Testing

Example product image for illustration purposes only, from Intuitive Surgical Website.

Summative Evaluation: Standard Practice Task Assessment

Conclusion Options after Standard Practice Assessment:

- No need to conduct HF Summative Validation Testing because the Task is Standard Practice.
- Need to conduct HF Summative Validation Testing because the Task is unique to the product and not Standard Practice.
- No need to assess simulated use in HF Summative Validation because manual aspects of task are Standard Practice; instead assess as a Knowledge Task since cognitive aspects of task are unique.

Note: You still need to conduct some testing (e.g., n=5) to verify that risk control measures are effective to ensure compliance with ISO 14971.

Threshold Analysis / Equivalency Justification

Summative Evaluation: Equivalency Justification

Conduct a Comparative Analysis

- To conduct a comparative task analysis, sponsors should
  - systematically dissect the use process for each product (i.e., for both the proposed product and the product it references) and
  - analyze and compare the sequential and simultaneous manual and cognitive activities for end-users interacting with each product
- FDA recommends that sponsors analyze the differences with the goal of characterizing the potential for use error
- Presenting this information in a side-by-side comparison table can help to facilitate FDA evaluation of this information

Summative Evaluation: Equivalency Justification Assessment

Comparative Task Analysis
(Highlight Differences/Similarities)

Create a Workflow

Identify Critical Tasks based on the Use-Related Risk Analysis

List all Critical Tasks in a Table

Expert Clinical Review →

Expert Usability Review →

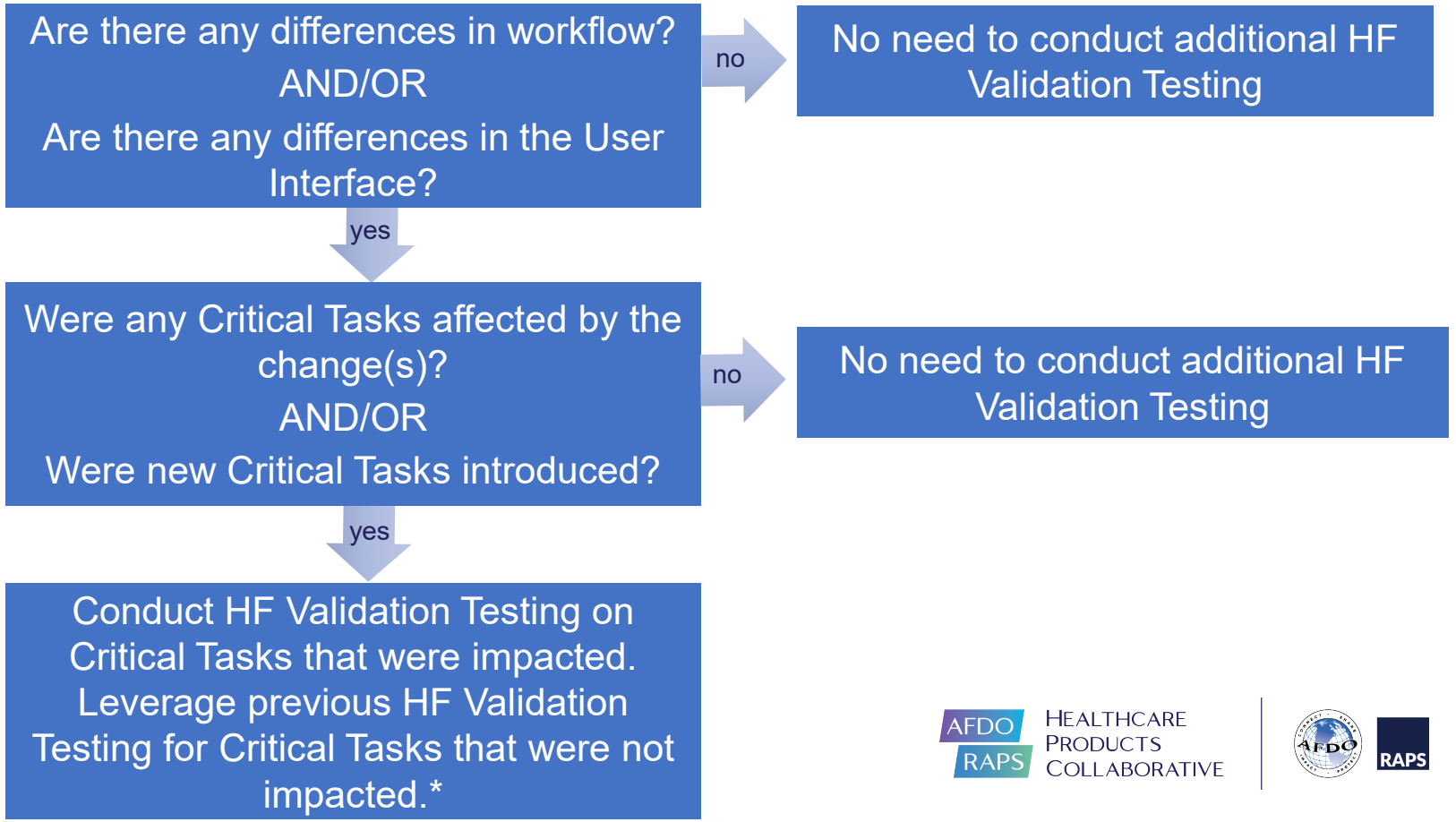
For Each Critical Task: Discuss How the Task is equivalent to
(1) Predicate product
or
(1) Earlier version of product

Compare User Interfaces
(Highlight Differences/Similarities)

Include Images discuss similarities to highlight equivalence, highlight differences

Summative Evaluation: Equivalency Justification Assessment

Conduct an Expert (Usability) Review of the Differences / Similarities that were Identified



Summative Evaluation: Equivalency Justification Assessment

Conduct an Expert (Usability) Review of the Differences / Similarities that were Identified

Are there any differences in workflow?
AND/OR
Are there any differences in the User Interface?

no → No need to conduct additional HF Validation Testing

yes ↓

Were any Critical Tasks affected by the change(s)?
AND/OR
Were new Critical Tasks introduced?

no → No need to conduct additional HF Validation Testing

yes ↓

Conduct HF Validation Testing on Critical Tasks that were impacted. Leverage previous HF Validation Testing for Critical Tasks that were not impacted.*

*Note: For minor differences, a Usability Expert may conclude minor impact on usability. Consider a smaller study to support your assessment.

*Note: You still need to conduct some testing (e.g., n=5) to verify risk control measures are effective for ISO 14971 - unless the same risk control measures are found in the equivalent product.

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On-Market Data Review

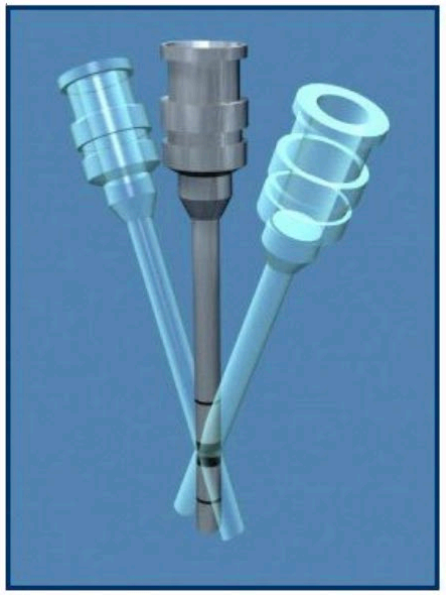
Clinical or On-Market Data Review

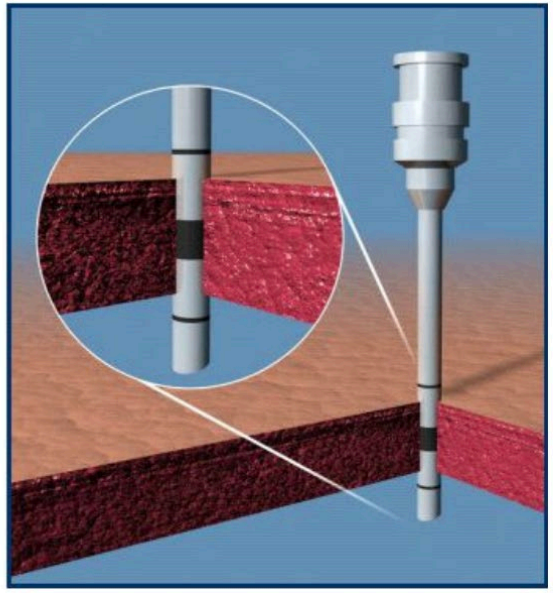
- **Can we use pre-clinical data (in animals) or in-human clinical data as "Summative Evaluation"?**
  - The problem with clinical testing is that the users are typically extensively trained, and
  - Clinical representatives from the company tend to monitor the session closely and intervene at times, biasing the user.
  - Due to the in-session bias and over-training, the FDA does not typically allow us to leverage clinical data to "count" as HF Validation /Summative Evaluation
  - Occasionally, FDA will allow observation of a specific task that cannot easily be simulated to support the other HF Validation Testing.

Clinical or On-Market Data Review

Example:

- Robotic Cannula marking must be centered on the body wall
- Animal body walls and simulators are not representative





Example product images for illustration purposes only, from Intuitive Surgical Website.

Clinical or On-Market Data Review

- If your product is on-market in Europe, a summary of complaints may be a powerful way to justify no further testing.
- However, the FDA has voiced concerns about differences between Europe and the US in hospital practices and user profiles.
- FDA buy-in should be gained before this approach is taken to minimize risks of submission delays while extra data is gathered.