

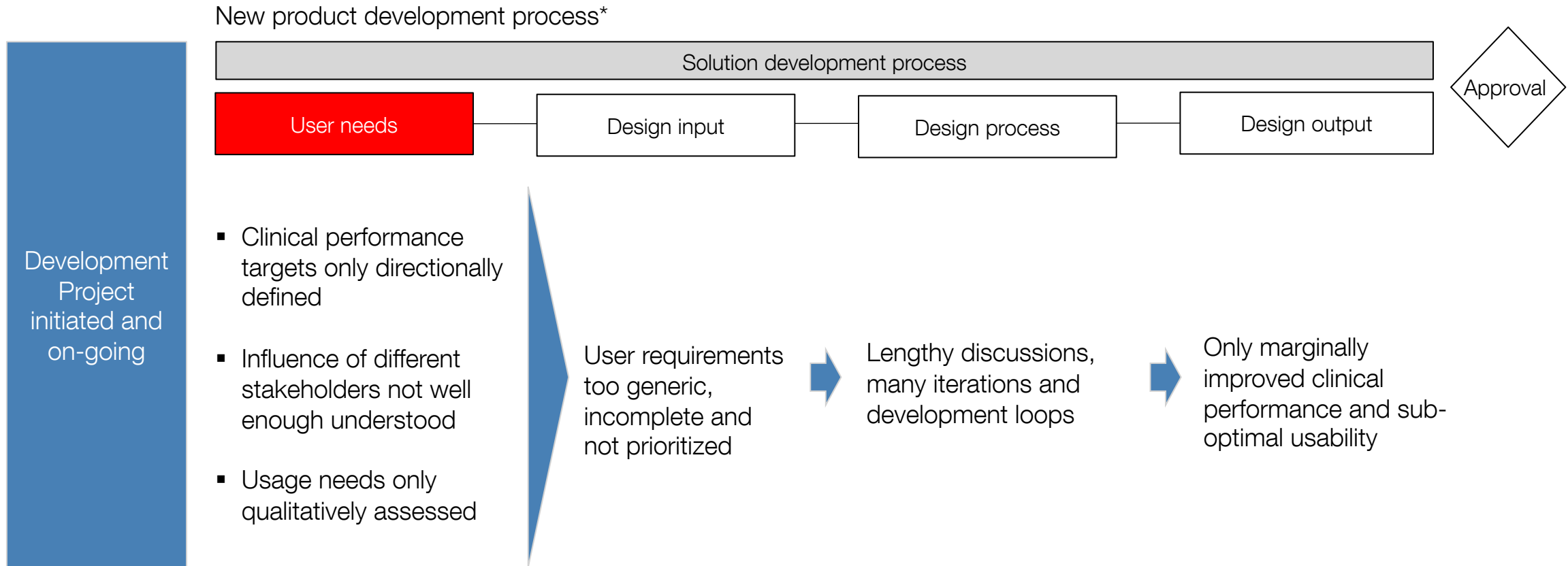
Specify user requirements based on stakeholder needs

Stakeholder-focused Innovation: A new approach for MedTech new product development
Zurich, March 2022

Spinning ideas to growth



The problem: Stakeholder needs are neglected and poorly understood in the development process



User understanding is required by standards in MedTech innovation, but often done too late or too light

The IEC 62366-1/2 norm



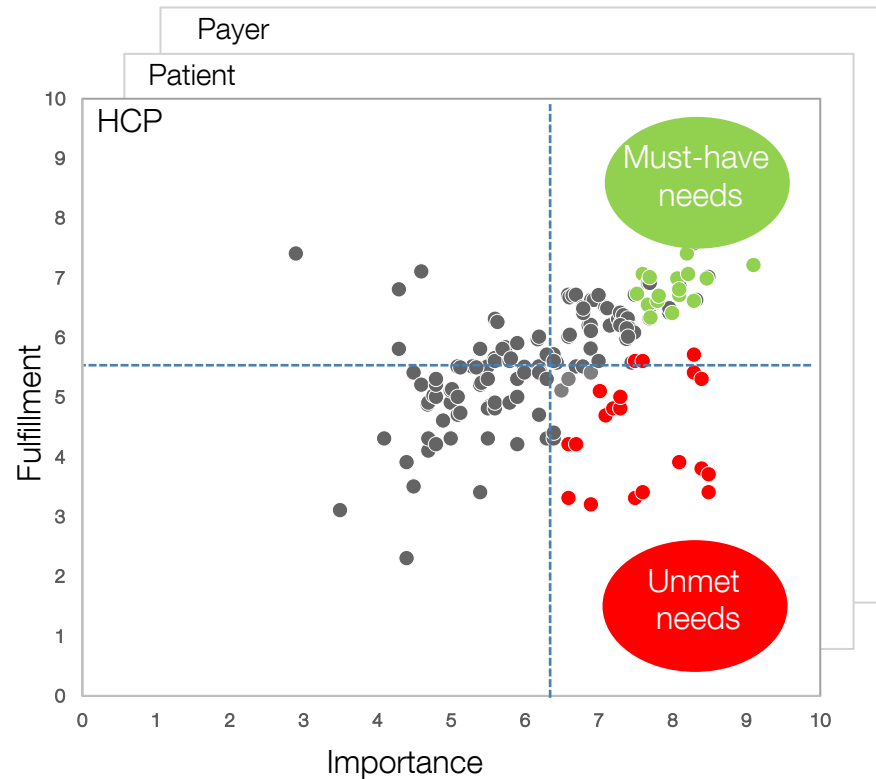
MedTech development standards

- require the application of usability principles during the development process
- intend to produce medical devices that satisfy users and lead to fewer use errors and less harm

Source: Introduction to IEC TR 62366-2

Define the user requirements based on stakeholder needs

Need Maps of stakeholders



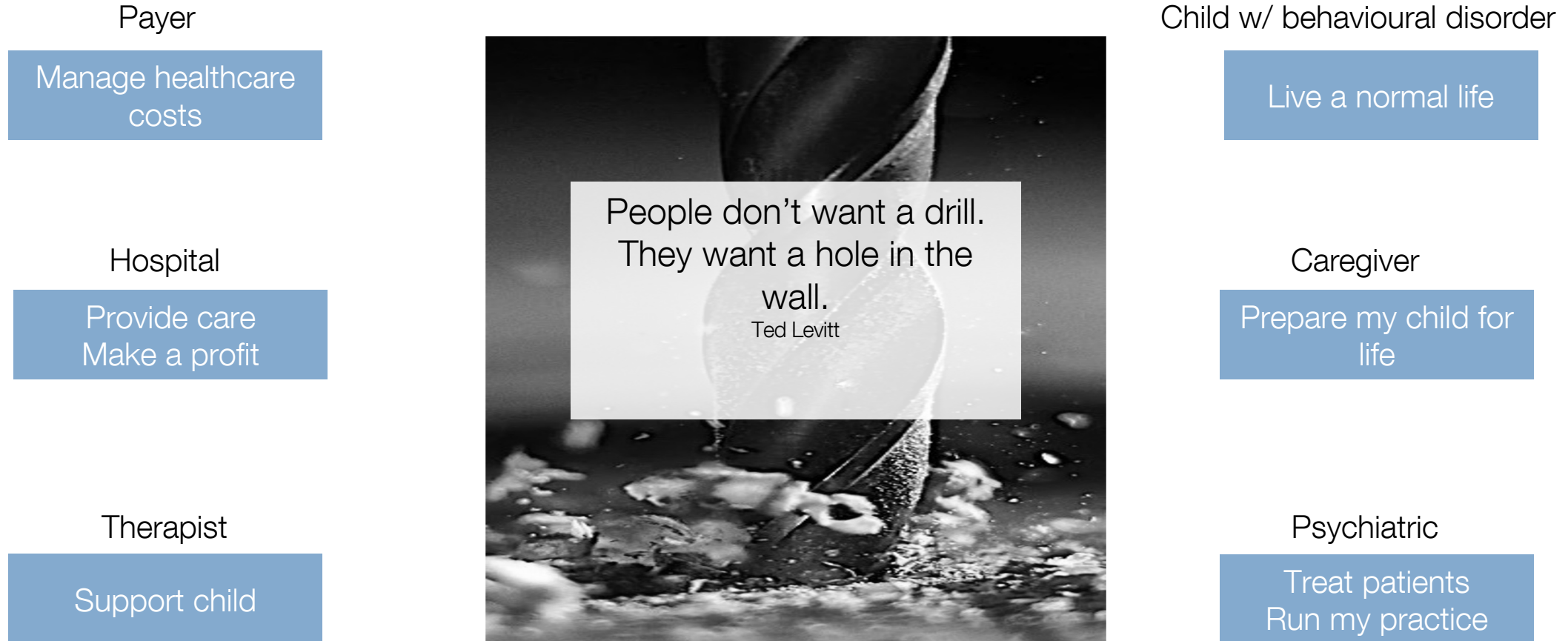
Need-driven requirement list



- Hardware
- Software
- Electrical
- User interface
- Others (partners, etc.)

Stakeholder-focused Innovation is based on Jobs-to-be-done, a powerful logic to take the stakeholders perspective

Example: Stakeholders and their Job for a digital therapy children with behavioural disorder



Source: Vendbridge Stakeholder-focused Innovation project for a pharmaceutical company, 2021

How it can drive adoption and engagement

Example: Digital therapy for children with behavioural disorder

Stakeholder Core Jobs

Caregiver

Prepare my child for life

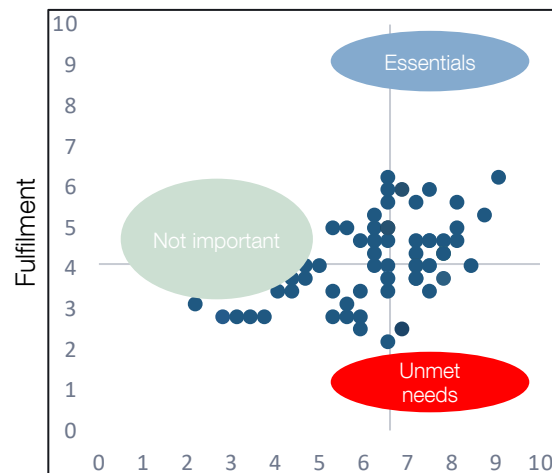
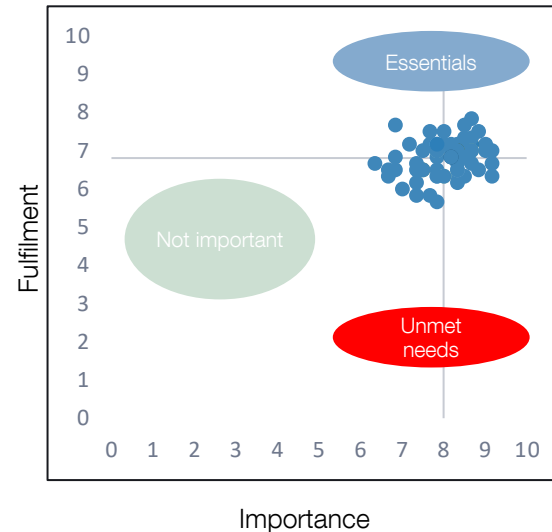
Live my other roles in life

Therapist

Support child w/ behavioral disorder

Run my practice

Value Maps

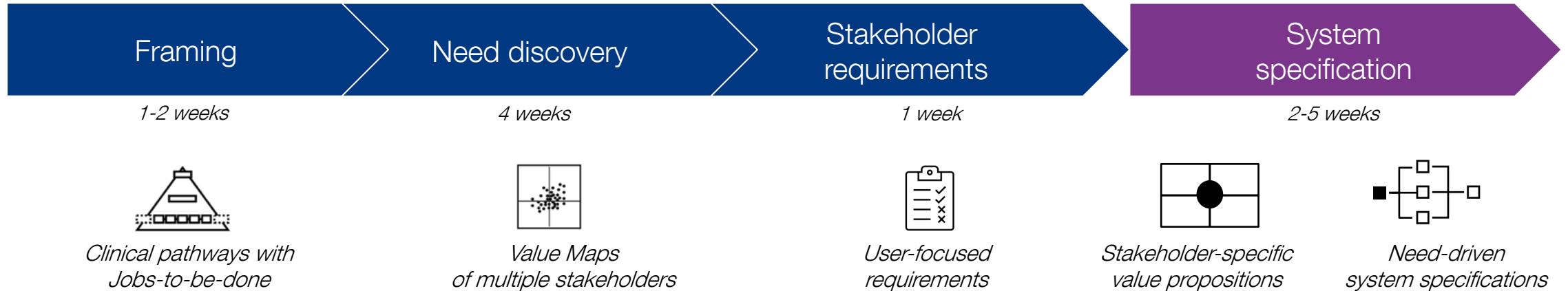


Key stakeholder insights for solution design

- Always worried when I am not with my child (e.g. when at work)
- Key concern that my child is not speaking-up when out of home (in school, in public transport, etc.)
- Constant latent fear that my child is getting depressed
- Difficulties to show parents the progress the child has made
- Use less time to plan the upcoming sessions with the child
- Be more confident when identify the next skill area to train

Process can be completed in 2-3 months

Systematic process with 4 steps



- Stakeholder Mapping
- Define intended purpose
- Frame with Job-to-be-done hierarchy

- Qualitative Jobs-to-be-done interviews with stakeholders
- Long-list of stakeholder metrics (= needs)
- Quantitative survey to prioritize unmet needs

- Translation of unmet needs into stakeholder requirements
 - Legal
 - Market
 - Organization
 - Performance
 - Use

- Trade-off decisions between conflicting needs

- Value propositions to gain market momentum via fast stakeholder adoption
- System specifications that build on prioritized requirements

Stakeholder-focused Innovation process elevates user research to the next level

Why Stakeholder-focused Innovation



1. Clear targets



2. Fewer iterations



3. Faster approval



4. Faster market adoption



5. No use errors



1. Unmet needs of stakeholders known at the beginning of the innovation process

2. Higher confidence what features to develop thanks to prioritized understanding of needs


3. Clinical performance advantage known and documented along the process

4. Relevant and compelling medical claims for the different stakeholders


5. Safe use of medical device as usability goals are met


Vendbridge in cooperation with mind4medical


About Vendbridge and mind4medical





- Experts passionate about addressing unmet customer needs
- Spinning ideas to growth via bringing customer focus
- Supporting multinational companies and technology start-ups
- Thought leader in Jobs-to-be-done; creators of CFI Customer-focused Innovation process
















































- Expert in risk-based medical device development and requirements engineering
- Thinks in data and entities, not in document
- Supporting companies and start-ups from idea to technical solution considering the state of the art in technology









Specify user requirements based on stakeholder needs

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