Involving users in the product development, the design and the marketing of medical devices

SnitkerGroup

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About SnitkerGroup

- Market leader in Scandinavia in usability, user research and user centricity.
- Member of the UXalliance – the global alliance for User Experience. - quality user research in more than 25 countries.
- Head-quartered and usability lab in central Copenhagen.
- Clients include fortune 500-companies.
- We run 50+ international usability projects and recruit more than 1000 respondents per year.
- Extensive experience in Health Care for clients such as DAKO, Boston Scientific, BK Medical, LeoPharma, Medicin.dk, The National Health Board, and in personas for national portals like virk.dk and borger.dk

Please refer to http://snitkergroup.com/ for a comprehensive presentation of the company.

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Have you ever…

…. googled a disease, your doctor or your hospital?

” 80% consulted the Internet for the choices related to their healthcare, on average three times per month”.*

” likely to visit healthcare sites: 66%. Financial information: 50%”*

* USA only, Harris Poll 2012

The eHealth revolution

The convergence of

- electronic medical records (EMRs)
- telemetric patient monitoring,
- in-home health care,
- disruptively inexpensive diagnostic devices, and
- the use of ubiquitous computing and mobile platforms.

“from an atom to a bit” (Negroponte)

”self-serve medicine”

“Quantified Self” (QS) or “Living by Numbers”

And what the eHealth revolution means…

…for the health care system

Digitalisation of Health Care

- EMR/Electronic Patient Journal

Change in the Health Care Professional's (HCP) job description

- Less facetime, more computertime

The aging population requires more funds for the HC sector

Health is information

- A push to provide relevant autoritative information

…for patients

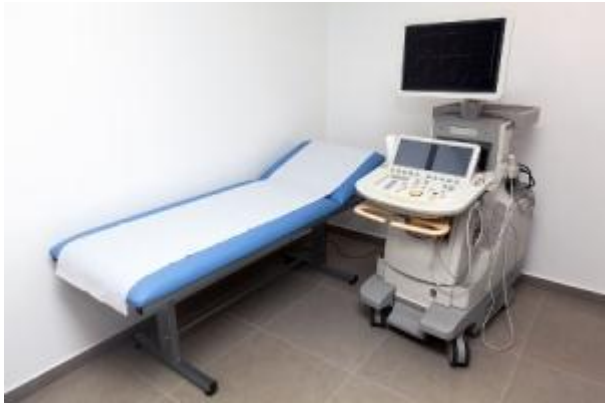
The smart phone

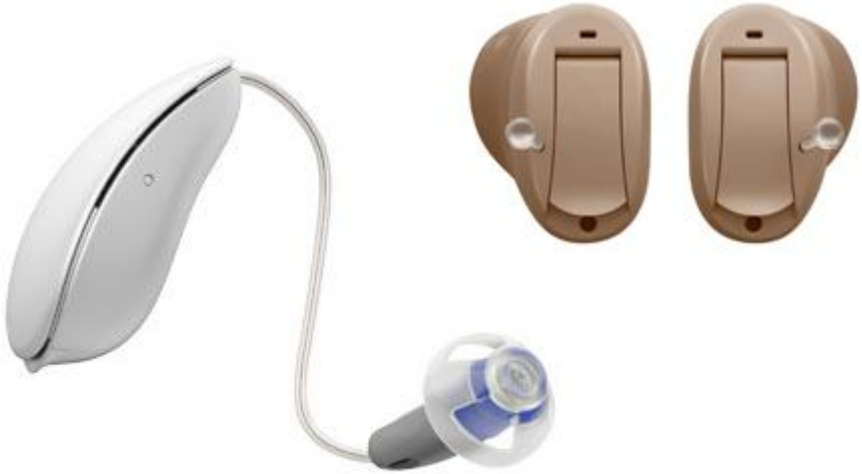
- Devices that allow patients to monitor themselves
- Increased need for intuitive user interfaces

Google (well, the internet)

- Patients will look for information on diseases.
- They will exchange experiences online (e.g. in forums)

Medical device usability





Specific challenges in medical device design

- Products are on the market for a long time 15 - 25 years – much longer than in other industries
- High investment cost
- Low availability of the device – hospitals dont have enough or dont know where the devices are located
- Reduced mobility of device
- Cost for cleaning, service and repair
- Risk of cross-contamination

Specific challenges in medical device usability

- Involving users in medical device design is a challenge
  - Hard to access the user and to fully understand their needs
  - Difficult to make sure that the device really works (safely and effeciently) without testing it with real users (patients AND HCPs)
  - Crowded market place where device manufacturers all talk to the same HCPs – lack of confidentiallity
  - Patenting an idea requires resources
  - Hard to get to a broad spectrum of end users (HCPs) – not just the experienced doctors
- Legislation and regulation curbs creativity
- Conservative business environment

Challenge: Different users

The user's ability to operate a medical device varies greatly:

- Professional (HCP) or not professionel (patient, relative)
- Professionals vary in background, title and responsibility, in domain knowledge and domain experience
- HCPs and non-professionals vary in age, physical abilities, sensory abilities, perception, cognition
- Non-professionals vary in mental and emotional state

Challenge: Different contexts

Usage contexts vary:

- Clinical context; hospital, clinic …
- Nursing; rehabilitation, long term care …
- Homes; and homes are different
- Work places, offices, schools, parks …
- Mobile/transport; plane, buses, trains, cars, ambulance …
- Varying infrastructure: room sizes, lighting, background sound levels, utilities …

Challenge: Different devices

The user's past experiences with user interfaces vary:

Data input:

- buttons, switches, keyboards, touchscreens ...
- commands

Data output:

- Visuals: displays, lights, controls, settings …
- Acustics: warnings, alarms, bips, voices, motors ...

THE REGULATIONS

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‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

▪ ▪ ▪

►B

COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

(OJ L 169, 12.7.1993, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998	L 331	1	7.12.1998
►M2	Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000	L 313	22	13.12.2000
►M3	Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001	L 6	50	10.1.2002
►M4	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
►M5	Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007	L 247	21	21.9.2007

Medical device regulations

- ISO/IEC 62366:2007 - Medical devices – Application of usability engineering to medical devices
- Usability engineering process, Accompanying document, Training

- ANSI/AAMI HE75:2009 – Human factors engineering – Design of medical devices
- General considerations and principles (Managing the risk of use error, Usability testing), Design elements (Controls, Software), Integrated solutions (Mobile medical devices, Home health care)

- Applying HF&UE to Optimize Medical Device Design (draft 2011)
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm

ISO/IEC 62366:2007

1. Specify how the medical device is used
2. Identify how the medical device is mostly used
3. Identify risks and potentially harmful or dangerous situations
4. Identify the primary ways of operating the medical device
5. Produce a usability specification
6. Prepare a usability validation plan
7. Design and implement the user interface
8. Verify the design of the user interface
9. Validate the usability of the medical device

TOWARDS A CURE

Applying a user centered design process we can…

involve the users to save costs and resources in:

… developing a device that solves no real need for anyone.

… trying to fix a device that users find hard to use.

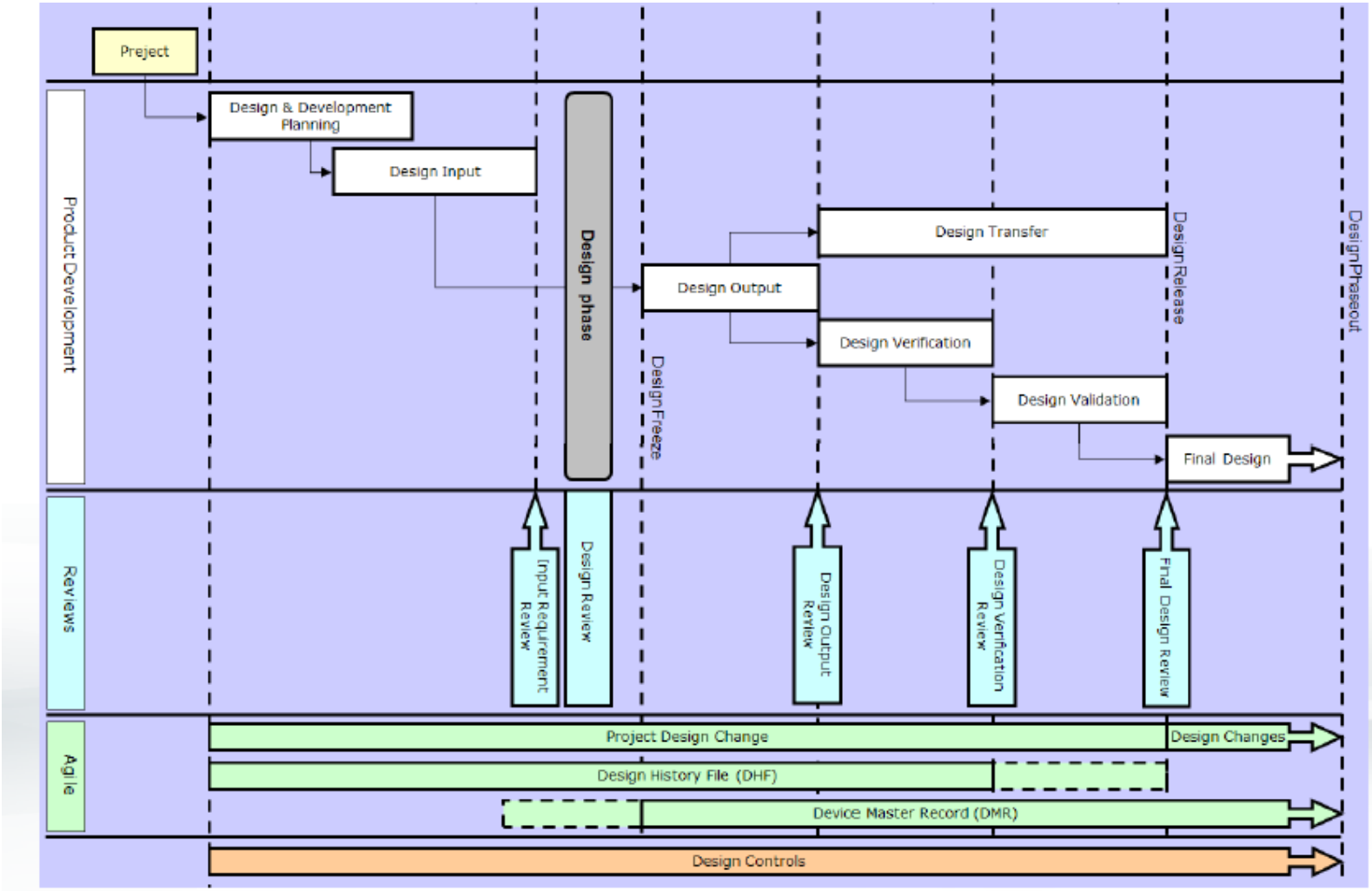
… supporting a device that users find hard to use

… compensating user dislike or even user rejection based upon their past problems using a device by the same manufacturer.

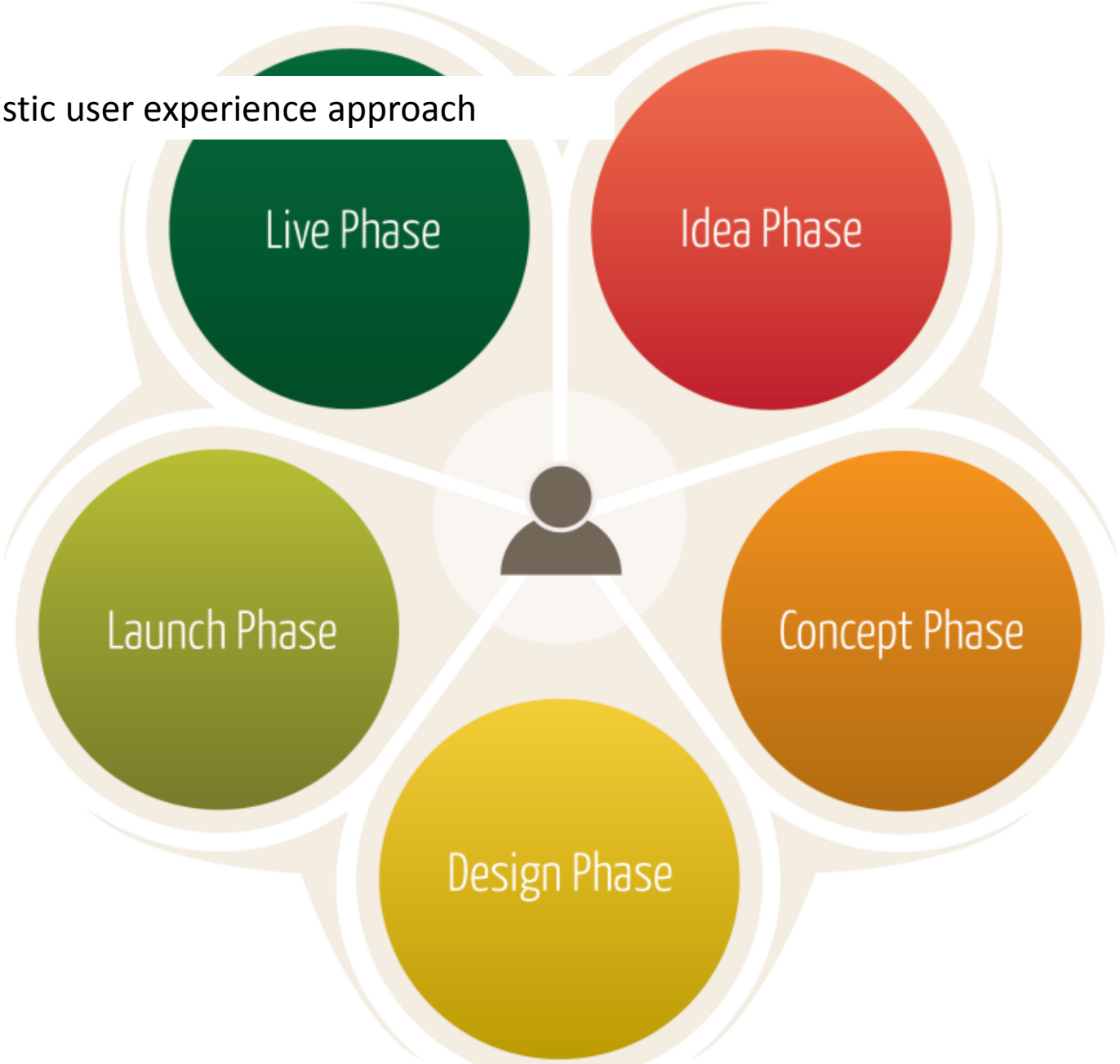
FAQ

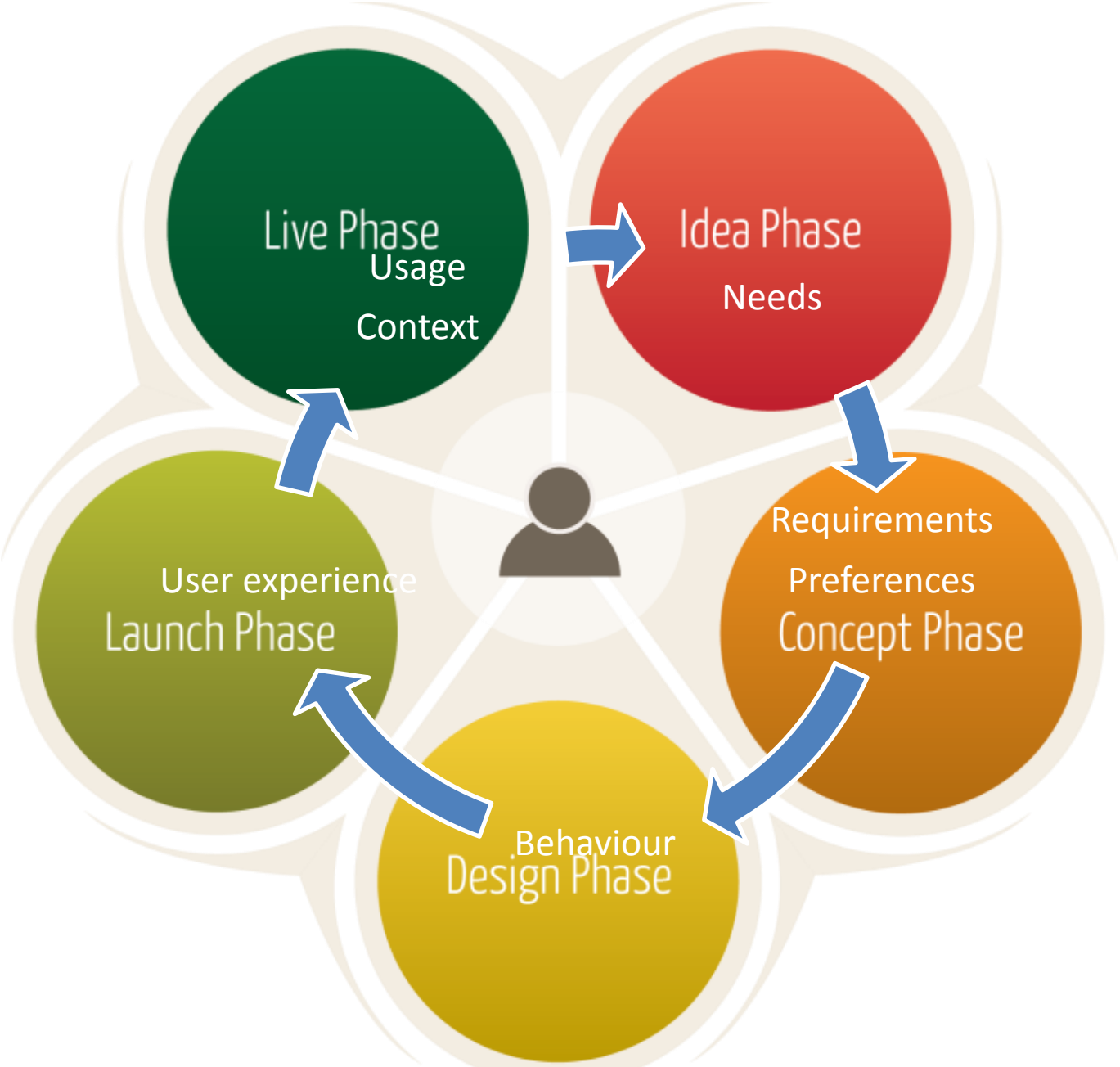
- When to involve users the best and the cheapest?
- How are our users the same, and how are they different?
- How to maintain a focus on the users throughout the entire process from idea to development and design to launch?
- How to ensure that all staff shares the same mental image of the users?

From a linear design and development approach …

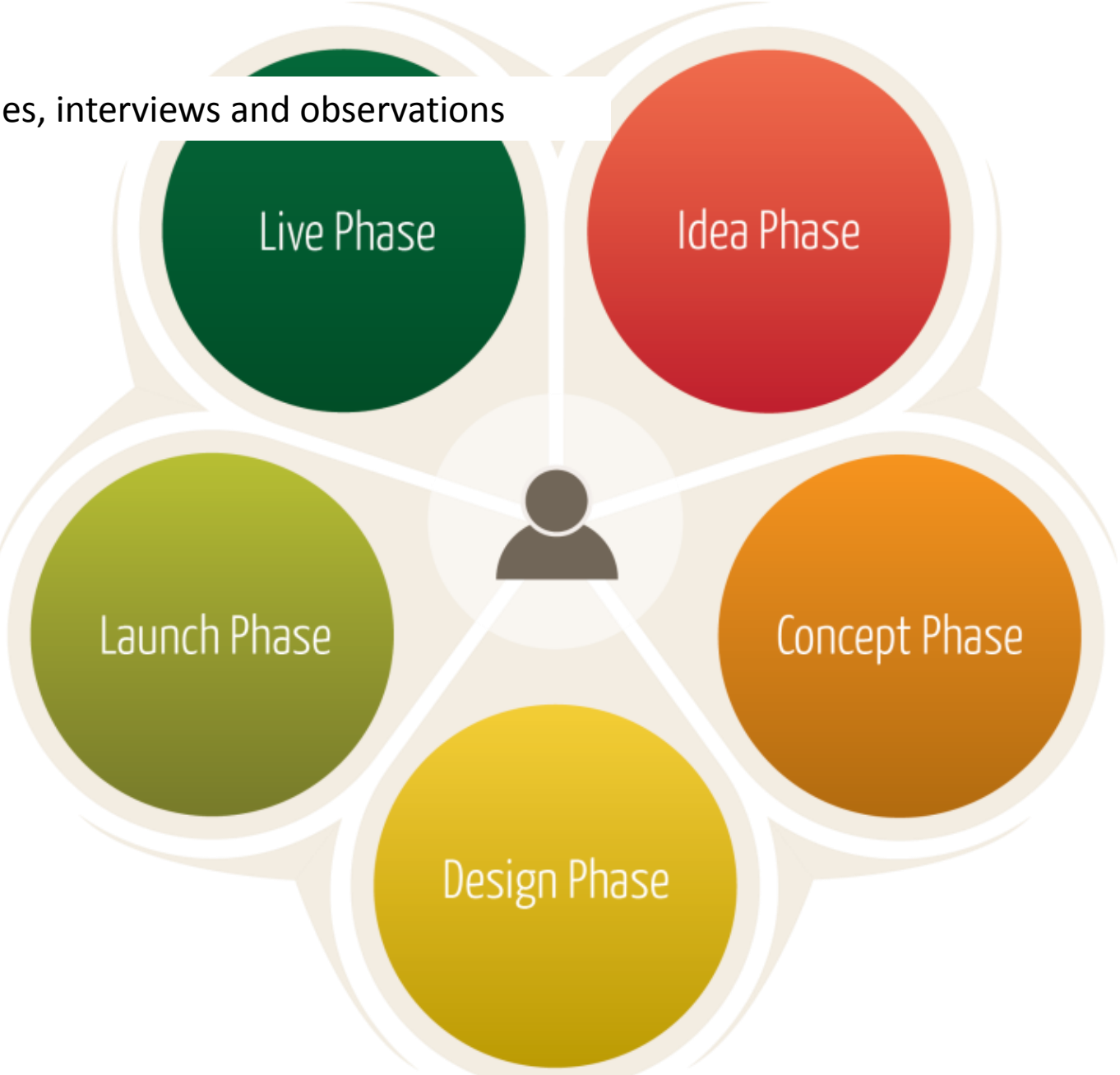


…to a holistic user experience approach



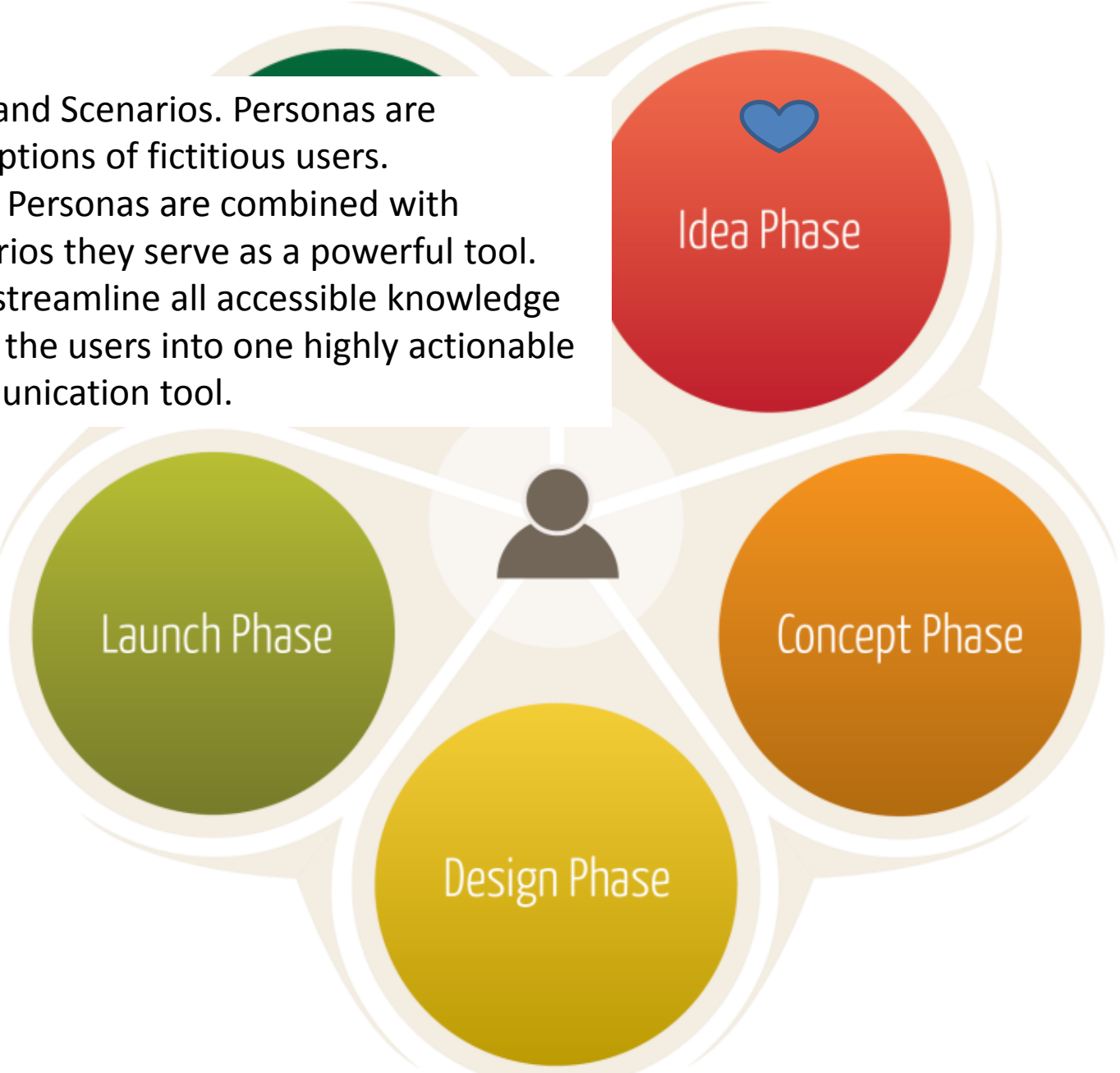

Live Phase
Usage
Context
Idea Phase
Needs
Requirements
Preferences
Concept Phase
Behaviour
Design Phase
User experience
Launch Phase

Field studies, interviews and observations



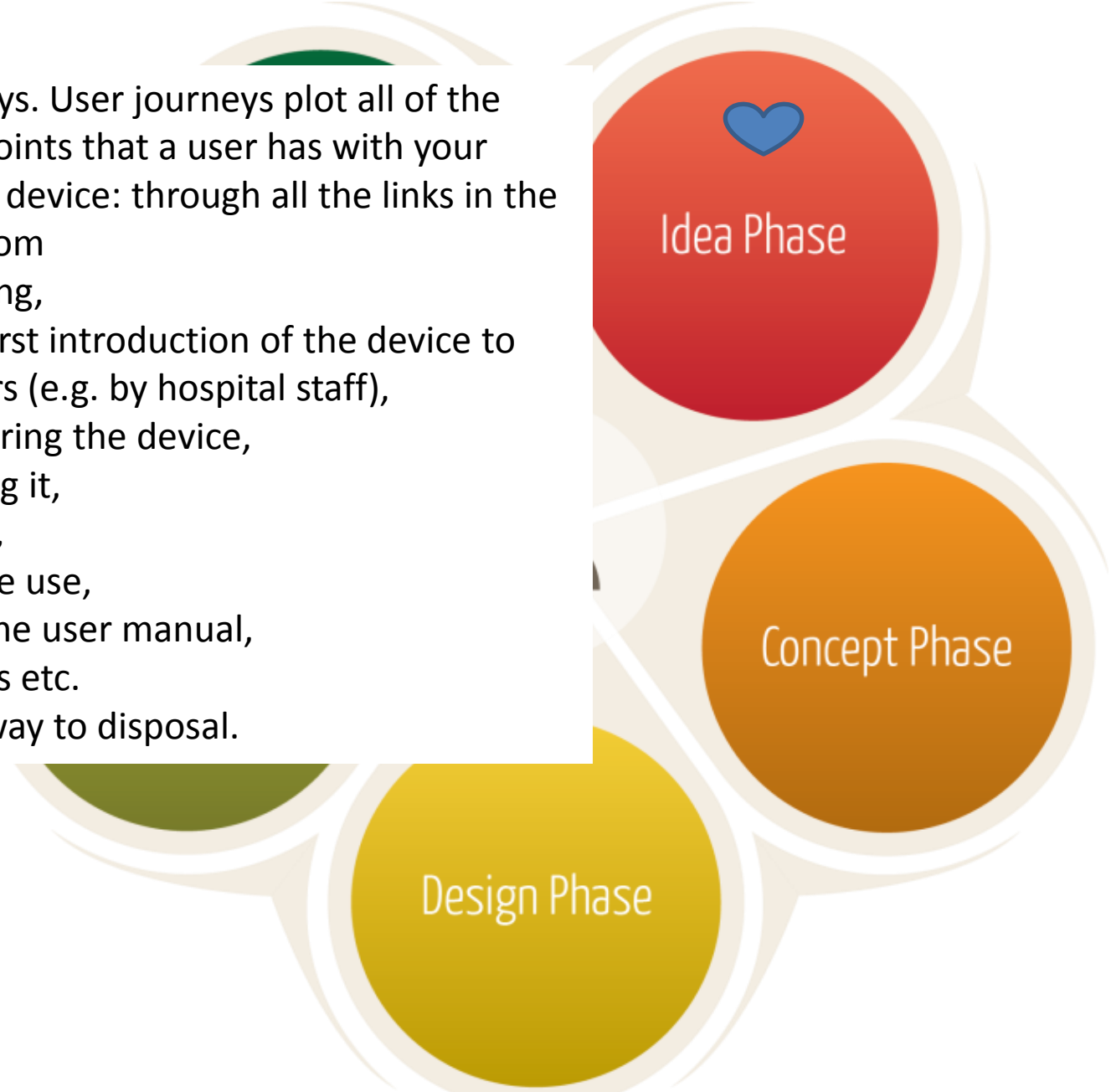
Personas and Scenarios. Personas are descriptions of fictitious users. When Personas are combined with Scenarios they serve as a powerful tool.

Personas streamline all accessible knowledge about the users into one highly actionable communication tool.

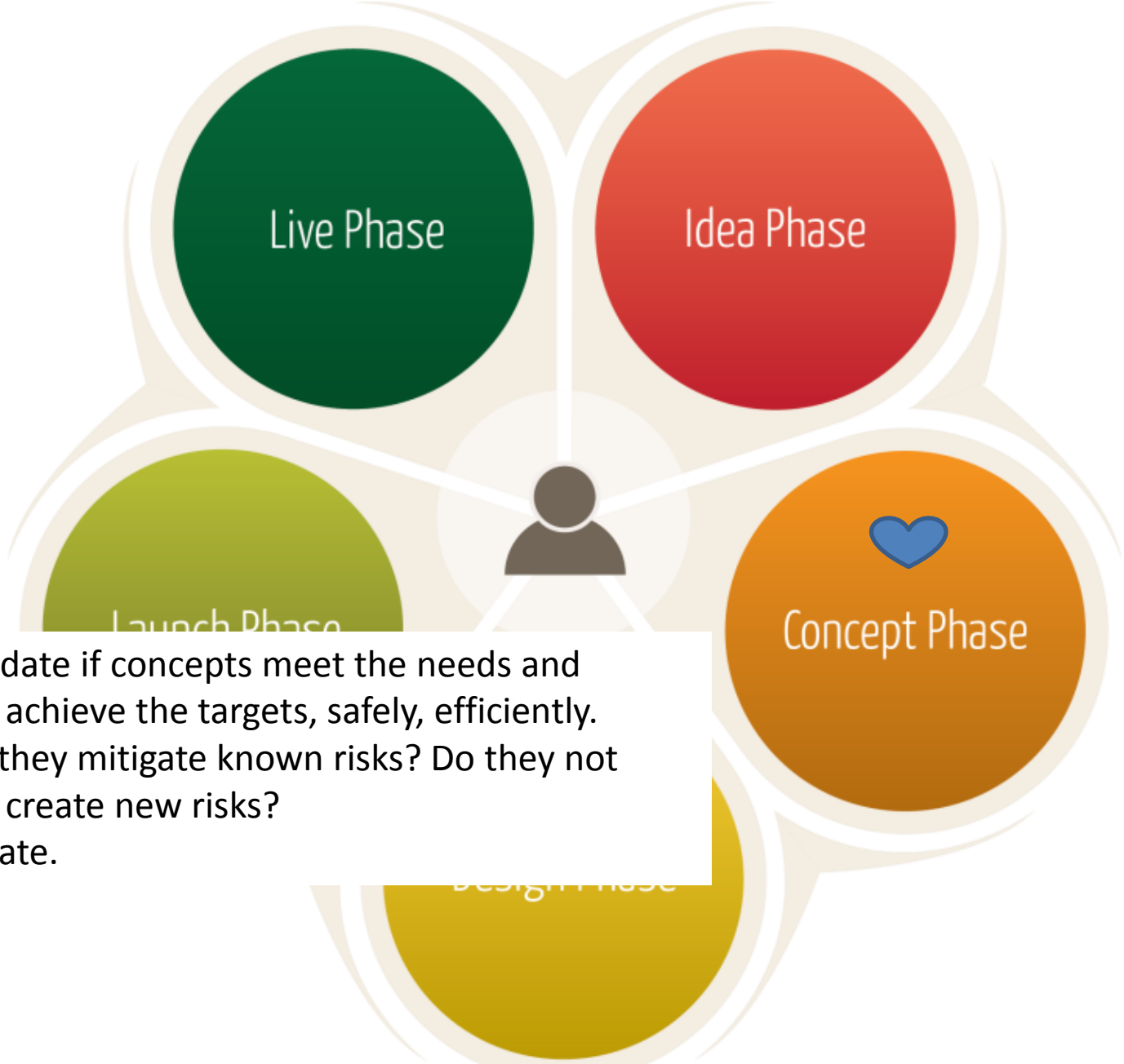


User journeys. User journeys plot all of the touch points that a user has with your medical device: through all the links in the chain from

- marketing,
- to the first introduction of the device to the users (e.g. by hospital staff),
- to acquiring the device,
- unboxing it,
- training,
- first time use,
- use of the user manual,
- websites etc.
- all the way to disposal.



User experience targets – setting targets for how users perceive and experience the device.



Validate if concepts meet the needs and achieve the targets, safely, efficiently.

Do they mitigate known risks? Do they not create new risks?

Iterate.

Validate if user interface designs meet the needs and achieve the targets, safely, efficiently.

Do they mitigate known risks? Do they not create new risks?

Iterate. Increase the level of realism – users, context, devices.

Usability testing (FDA and ISO 62366)

Evaluate user experience targets – do we meet the targets for how users perceive and experience the device?

Key points

- The eHealth revolution – new challenges in health care
- Medical device design is highly regulated
- We do have many ways to involve the users from the Idea Phase to the Live Phase.
- This can save costs and resources, and ensure safe and efficient use.

Connect!

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