konplan

Learnings from medical device startups consulting
-
Why we should embrace systems engineering

September 6, 2021

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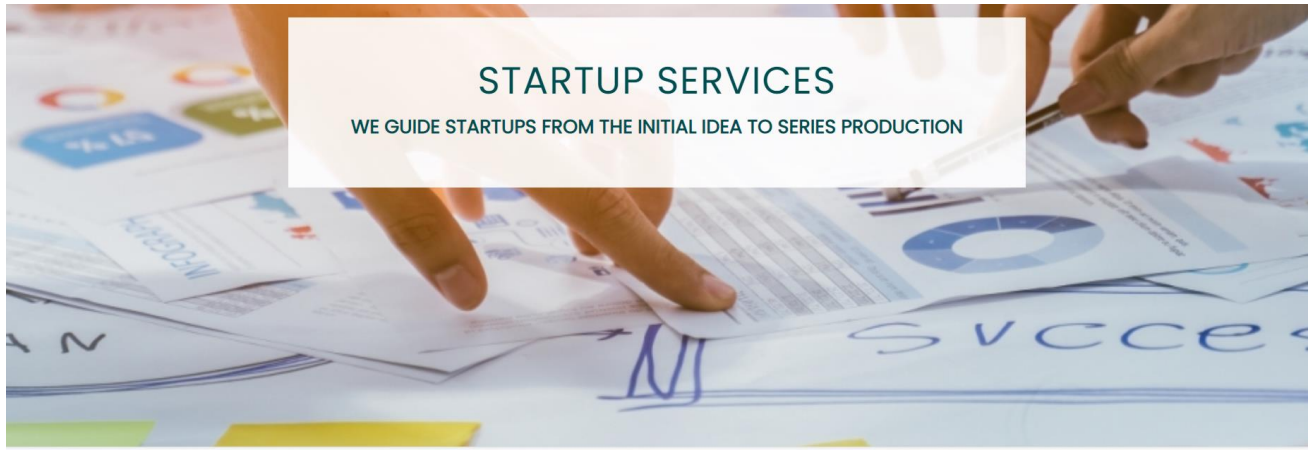
konplan systemhaus ag

konplan – affinity to startup support services



PORTFOLIO

PLANNING WORKSHOP
Planning workshop with roadmap and milestones up to market approval incl. Cost and time expenditure for investor pitch

RAPID PROTOTYPING
Rapid prototyping, feasibility studies, for example, using 3D-printing models

REQUIREMENTS ENGINEERING
Preparation of the requirements document; Standards-compliant requirements engineering

DESIGN TRANSFER
Design transfer to series production, concept testing, and test automation

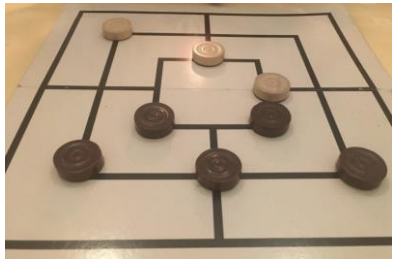
RISK MANAGEMENT
Risk management, Audit preparations

APPROVAL PROCESS
Guiding the approval processes (MDR, FDA, ...)

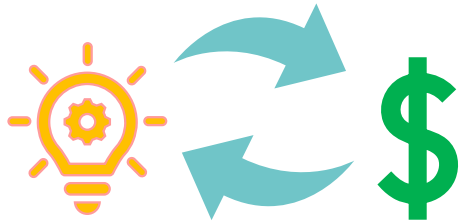
Locations

- Rotkreuz, CH (60 employees)
- Mannheim, DE (35 employees)
- Donauwörth, DE (10 employees)
- Odessa, UA (6 Freelancer)

Challenges of a regular startup…



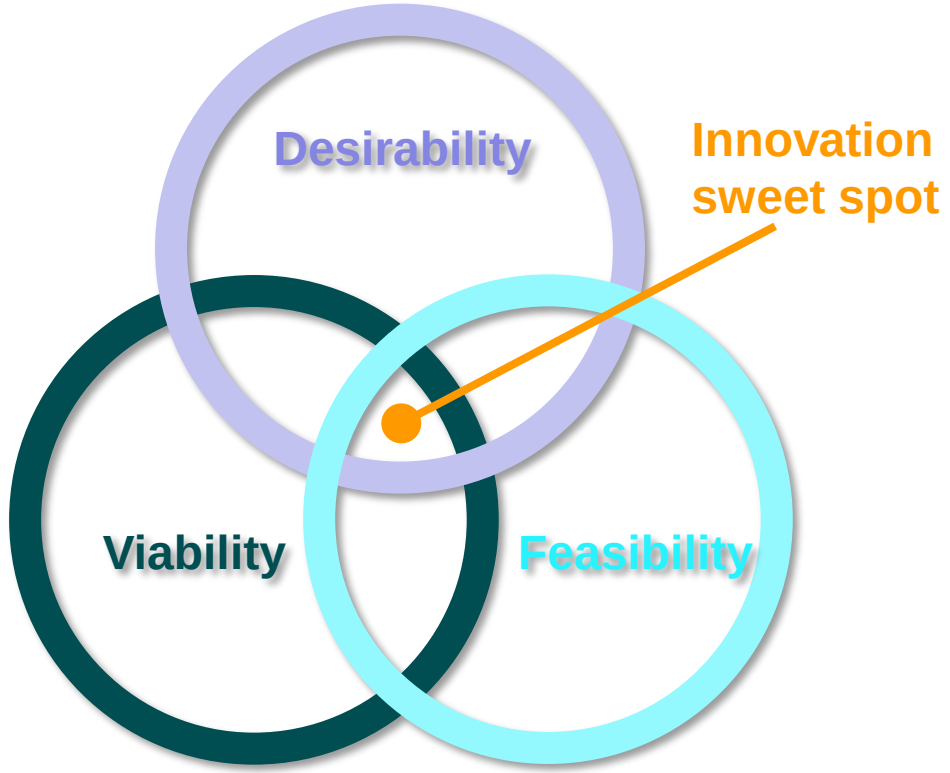
- **First: Brilliant idea**
- **Catch22 Situation**
  - Funding needed to get from idea to proof of concept
  - Proof of concept needed to get funding



- **Overwhelming amount of issues**
  - Getting funding, funding, … and funding
  - Young teams, team forming while growing (1-5, 5-25, 20-50, 25-100, 100+)
  - No processes, no defined responsibilities
  - Know-how gaps (market, regulations, technology, processes, administratives, etc.)
  - …
  - How to set priorities?
- **Finding the sweet spot**

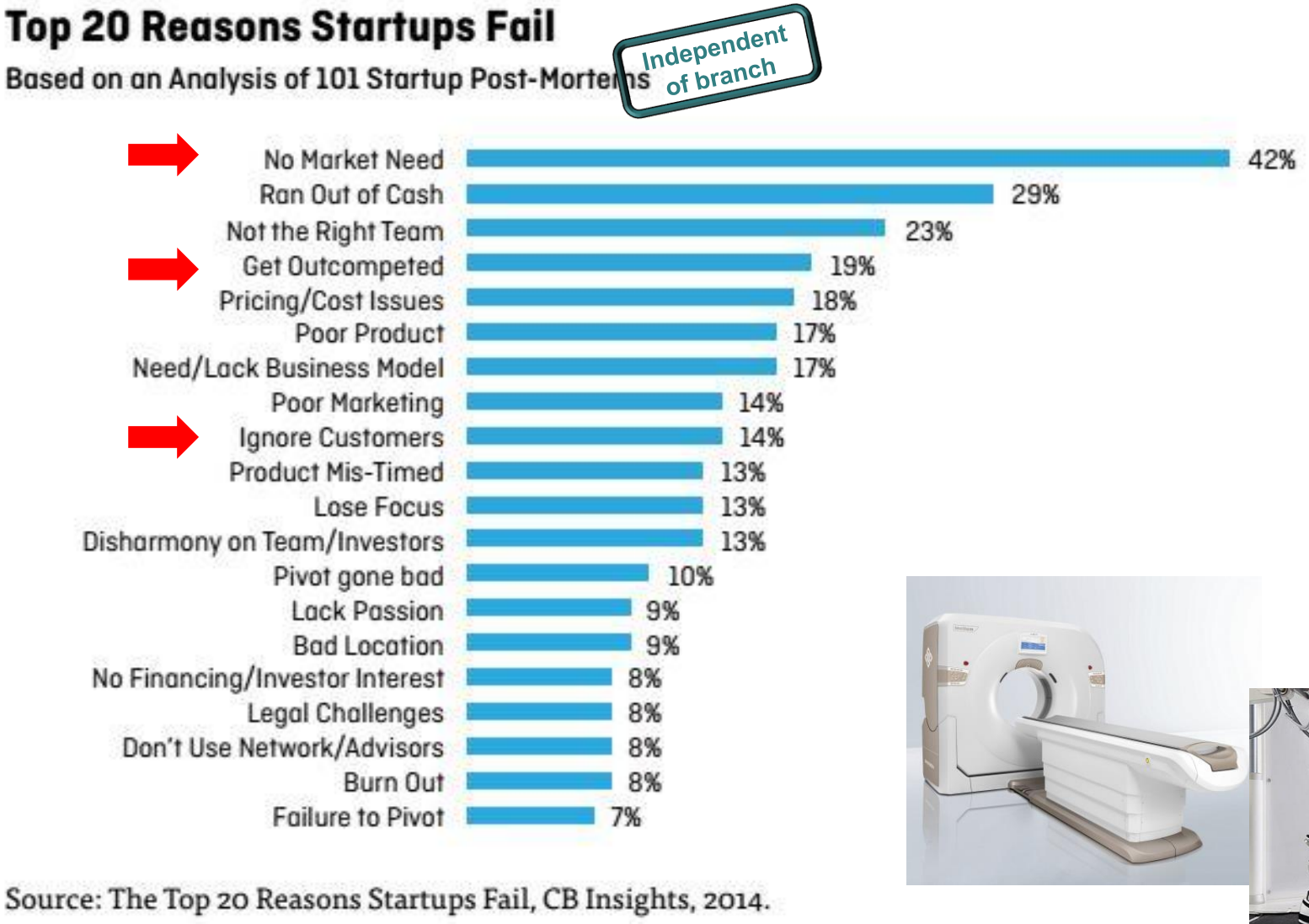
For a successful product… and company

- **Product desirability**
  - Customer / Market will purchase the product!
  - E.g. user interface, benefit offer
- **Viability**
  - Business model
  - E.g. margin (product pricing vs. production costs + distribution + marketing) positive on the long term
  - E.g. Intellectual property
- **Feasibility**
  - Product must be technically feasible



Video “Pretotyping”: Alberto Savoia

Why Start-Ups fail…



Healthcare market

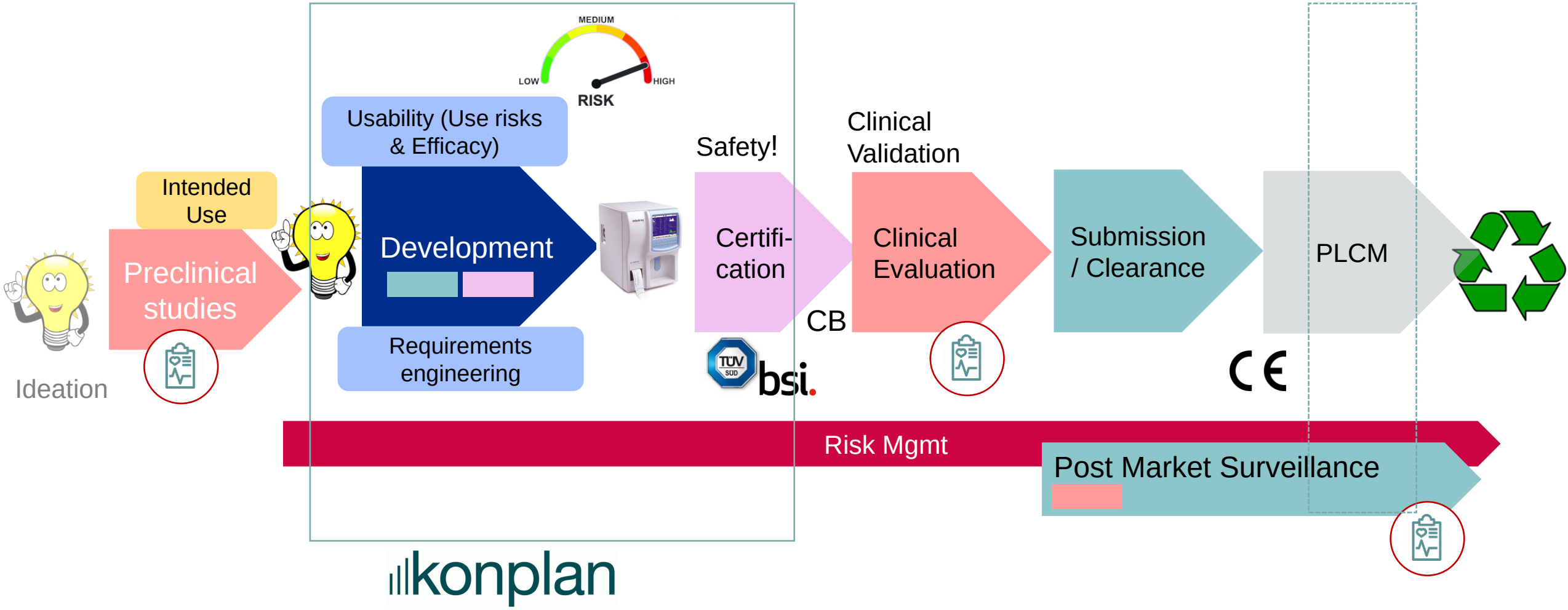
Healthcare branch

1) Forgetting patients and diversity
2) Not taking into account care providers
3) Difficulties in creating clinical value
4) No scientific validation
5) Overclaiming what technologies can do
6) Forgetting to go where users are
7) The solution is not cost-effective enough
8) Forgetting the ways of implementation
9) Forgetting healthcare is a slow beast
10) Being way too early or way too late

[10 Reasons Why Digital Health Start-Ups Go Bust - The Medical Futurist]

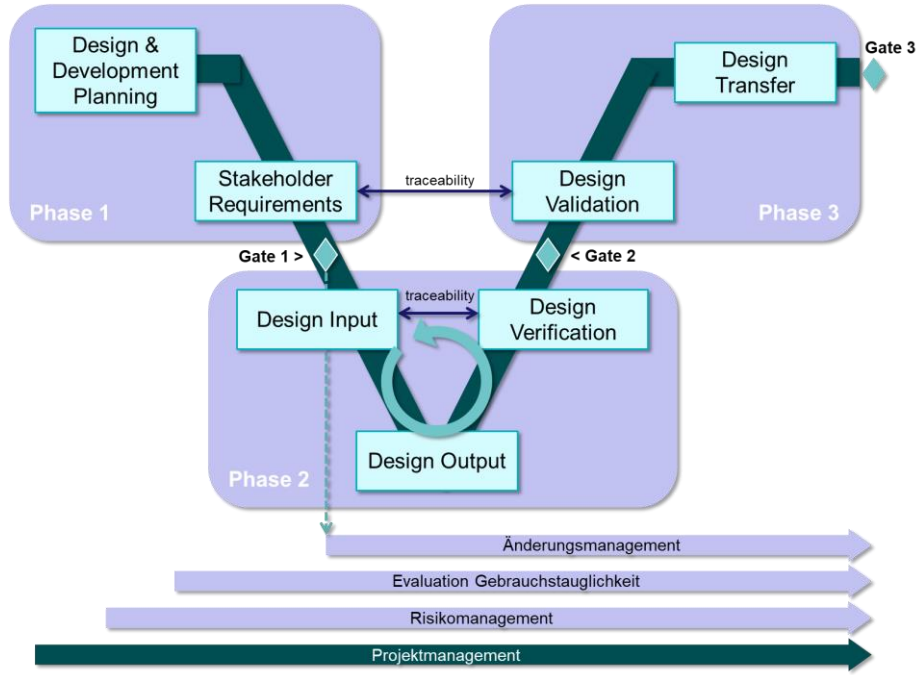
What phases konplan supports during the MD Life Cycle

Regulatory Affairs
Quality Assurance
Clinical Affairs

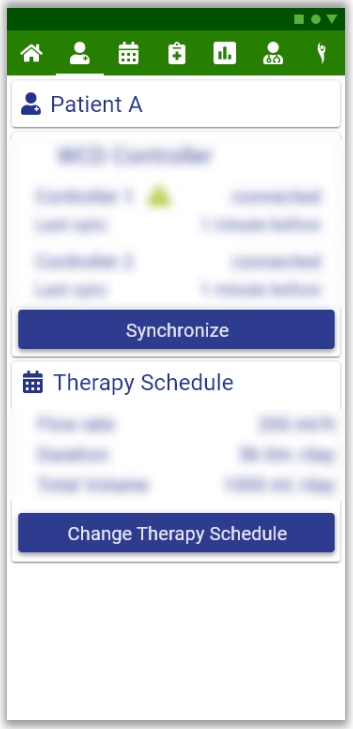


The course of success is set at the beginning…

- **Identify stakeholders along the entire lifecycle of the medical device, e.g. for PMS**
  - Intended use and use specification (context) elaboration
  - Stakeholder requirements definition and structuring
  - ➔ Arriving at an early MVP, avoiding large number of “prototypes”
  - ➔ Human factor engineering is not optional. Early validation
- **Creating awareness of the company’s core IP**
  - E.g. Hardware vs. Software
- **Creating awareness of blind spots**
  - E.g. technical / clinical vs. business view
  - Lack of sustainability: market potential vs. product price
  - Adhere to causal process flow, e.g. risk management activities



Example: Medical mobile app development project



Initial state:

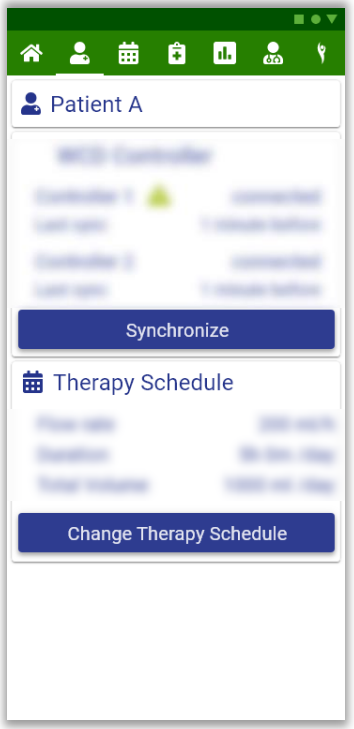
- Goal: Development of a mobile app to control a medical device
- Many requirements available on client's side; mix of stakeholder, system requirements and constraints
- Timeline: 2Mts

Requirements Management

- Restructuring of requirements of entire system; elimination of contradictions and duplications; make them measurable; challenge constraints: e.g.
  - "The product MUST be compatible with everyday activities" ➔ list of particular use cases
  - "The product MUST remain functional at least 1 year" ➔ provide rationale
- Rephrasing of requirements (syntax), solution neutral phrasing
- Introducing risk-based requirements management: e.g.
  - "The product MUST be MRI compatible." ➔ identify risk and define requirement derived from risk control measure
- Closing requirement gaps along the user journey (and product life cycle)

➔ Arrival at a set of requirements for the **MVP** enabling the mobile app development

Example (cont'd): Architecture



Architecture definition: among others, use of

- Data structure diagrams (entity relationship)
- Data flow diagrams and visualization (mock-ups)

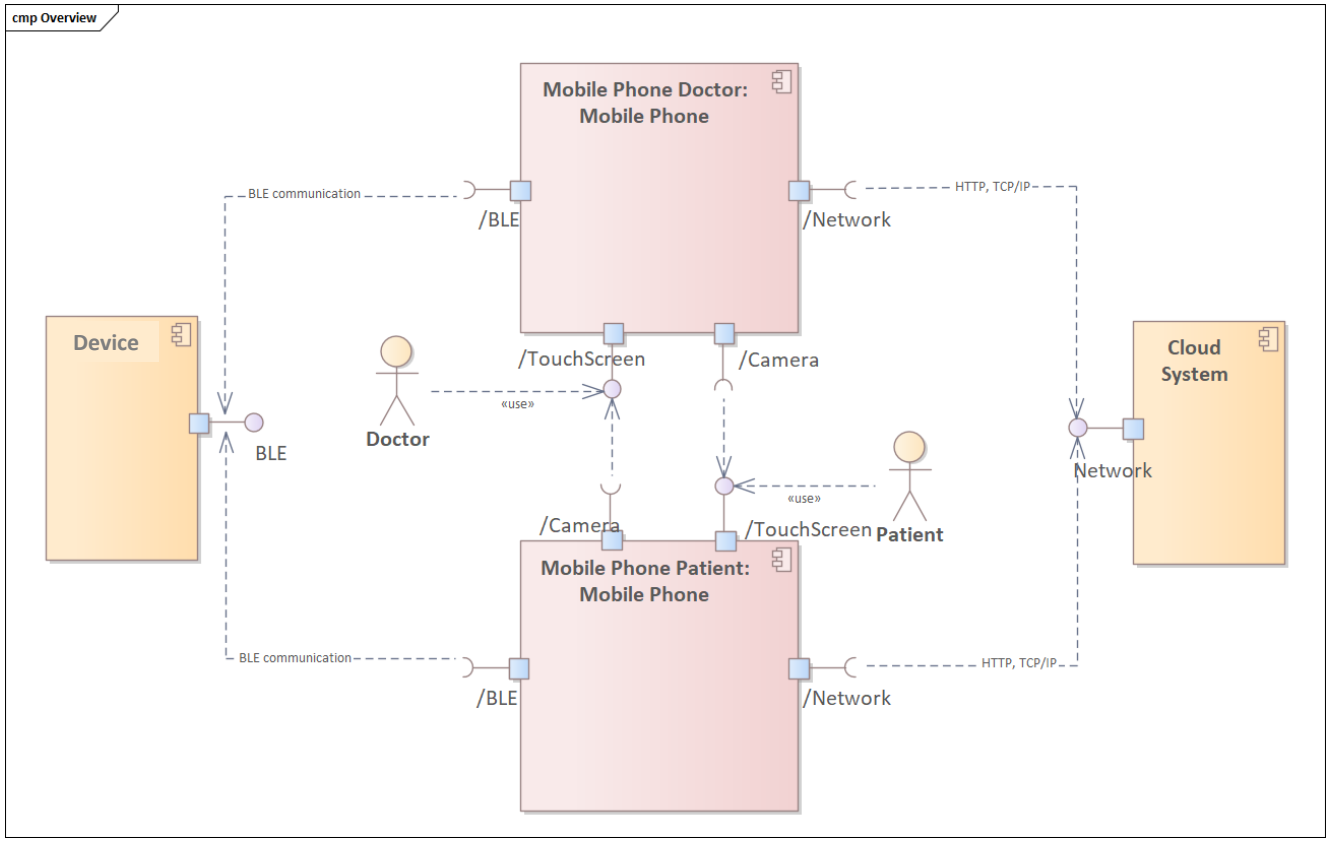
Making it obvious that:

➔ Cloud database required

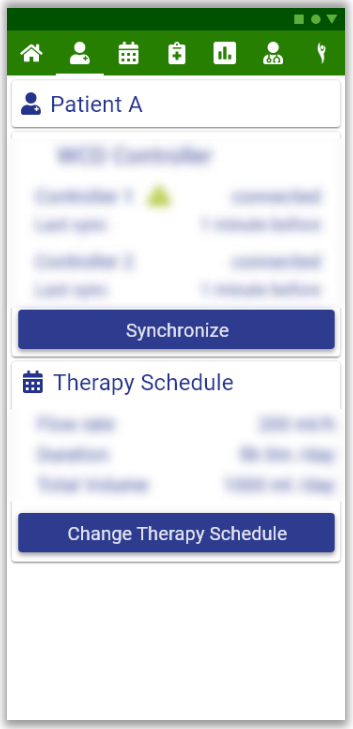
➔ 2 mobile apps (for patient and doctor) required instead of 1 mobile app

➔ Resulting in:

- Common UI
- Code base "platform"



Example (cont'd): User interface



Mobile App user interface evaluation:

- Weekly iterations involving konplan, client and students
  (not an ideal setup)
  - ➔ Usability
  - ➔ Bug tracking

Mobile App validated in a Human Factors study involving 8 external participants

- No use errors occurred
  (thus, no unacceptable risks occurred)

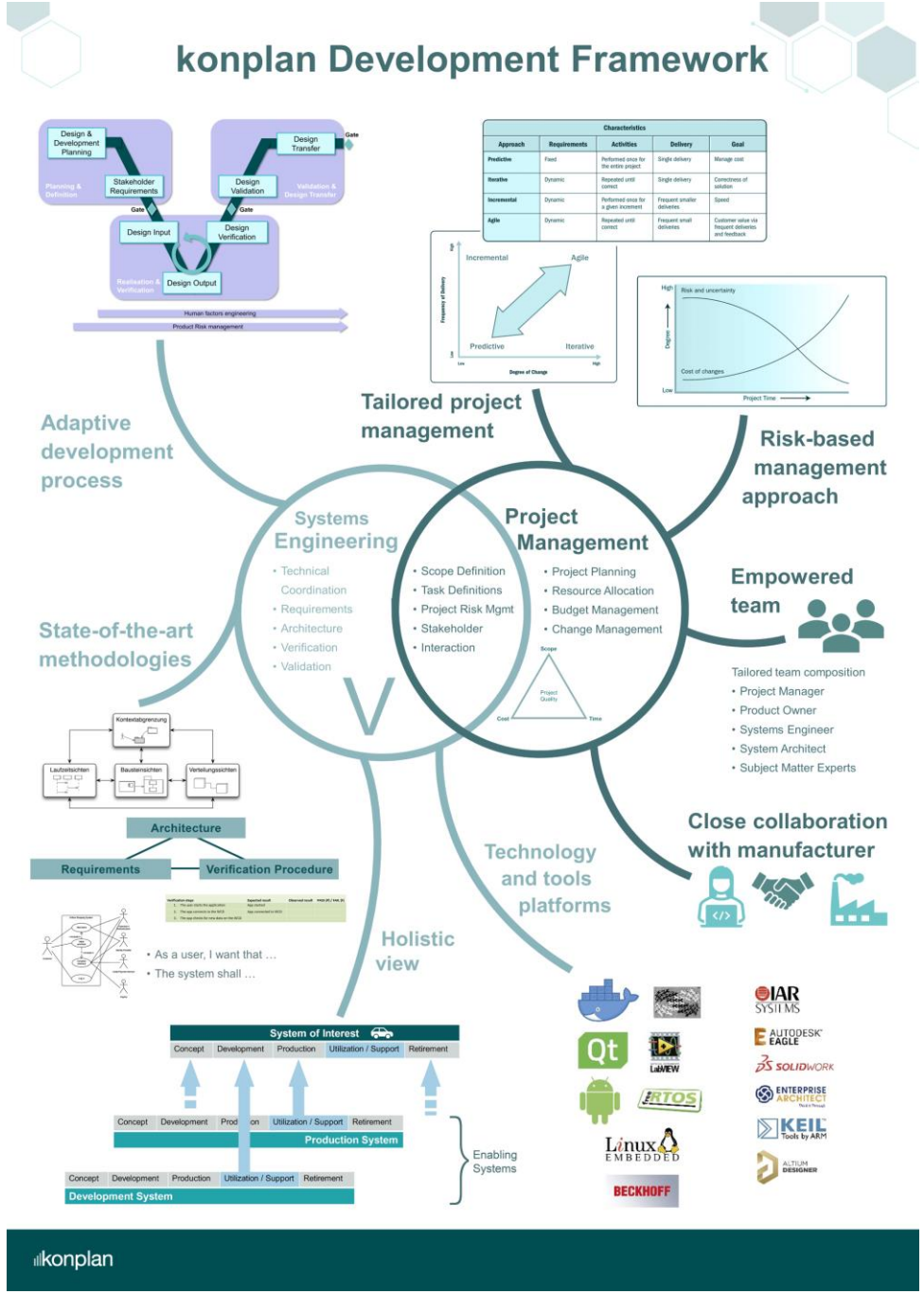
konplan offer within its framework:

Workshops to

- Provide holistic view on product idea
- Elaborate value proposition
- Identify gaps, risks and to define action plan
- To frame a project plan

Development of systems consisting of

- Software (PC, Cloud, Mobile)
- Electronics, firmware, packaging
- Mechanics (plastics, metal)
- Requirements engineering
- Risk management



Questions?

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Schon mit uns vernetzt?