Designing Your Medical Product: 5 Critical Steps

A GUIDE FOR HARDWARE AND SOFTWARE HEALTHCARE STARTUPS

FLUID

From idea to compliant prototype - faster.

Turning a promising healthcare idea into a real product **takes more than vision**.

Startups in MedTech, Digital Health, or BioTech face complex design and regulatory challenges - from defining a viable product strategy to navigating compliance and investor expectations.

At FLUID, we've helped startups across Europe and the US bring regulated medical hardware, connected devices, and digital health applications to life.

This short guide outlines the **five critical steps** to design a medical product that's fundable, user-centered, and ready for regulatory validation

"The earlier you connect design, usability, and compliance - the faster you move to market."

Step 1 | Define the Problem, Not Just the Product

Clarify the clinical problem and user context.

Many healthcare startups jump straight into features or device concepts. A common mistake is to develop a product first and then start understanding the needs of their customers.
The most successful ones start by **understanding the workflow, user pain points, and clinical setting first**. This forms the foundation for every design and regulatory decision.

Key actions:

- **Map the user ecosystem: clinicians, patients, technicians, IT staff.**

- **Observe the workflow in context (clinic, lab, home).**

- **Translate insights into design requirements and risk considerations.**

FLUID Tip:
In regulated environments, early user research directly supports ISO 62366 usability documentation - it's not just UX, it's compliance.

Step 2 | Shape a Viable Product Strategy

Balance desirability, feasibility, and compliance.

Once the problem is clear, define your product's value proposition and regulatory pathway.
This is where your design, engineering, and business goals must converge.

Key actions:

- **Clarify the intended use and risk classification (MDR/FDA).**

- **Define the core product architecture - hardware, software, or hybrid.**

- **Identify what belongs in the Minimum Viable Product (MVP) for validation or funding rounds.**

- **Align your roadmap with design control milestones.**

FLUID Tip:
Investors love clarity. A well-defined product vision with regulatory awareness signals maturity and lowers perceived risk.

Step 3 | Design for Humans and Systems

Translate complexity into intuitive user experiences.

Whether it's a connected diagnostic device or a clinical data platform, usability drives adoption.
In healthcare, that means designing for clarity, error prevention, and workflow integration.

Key actions:

- **Use human-centered design to simplify interaction.**

- **Create early UX wireframes or device interface mockups.**

- **Test with representative users - even at low fidelity.**

- **Ensure your design supports data integrity and safety-critical interactions.**

FLUID Tip:
For combined HW+SW systems, visualize the entire touchpoint journey - physical, digital, and service layers.

# Step 4 | Prototype, Test, and Learn

Make it tangible - fast.

A prototype turns assumptions into evidence.
It helps you convince investors, engage partners, and gather validation data - all while informing your technical roadmap.

Key actions:

- **Build physical prototypes (3D prints, looks-like/works-like models).**

- **Create interactive digital mockups or simulations.**

- **Run structured formative usability tests.**

- **Iterate based on insights — capture learnings for regulatory documentation.**

FLUID Tip:
Document every test. Even informal evaluations can later feed into your usability engineering file or risk analysis.
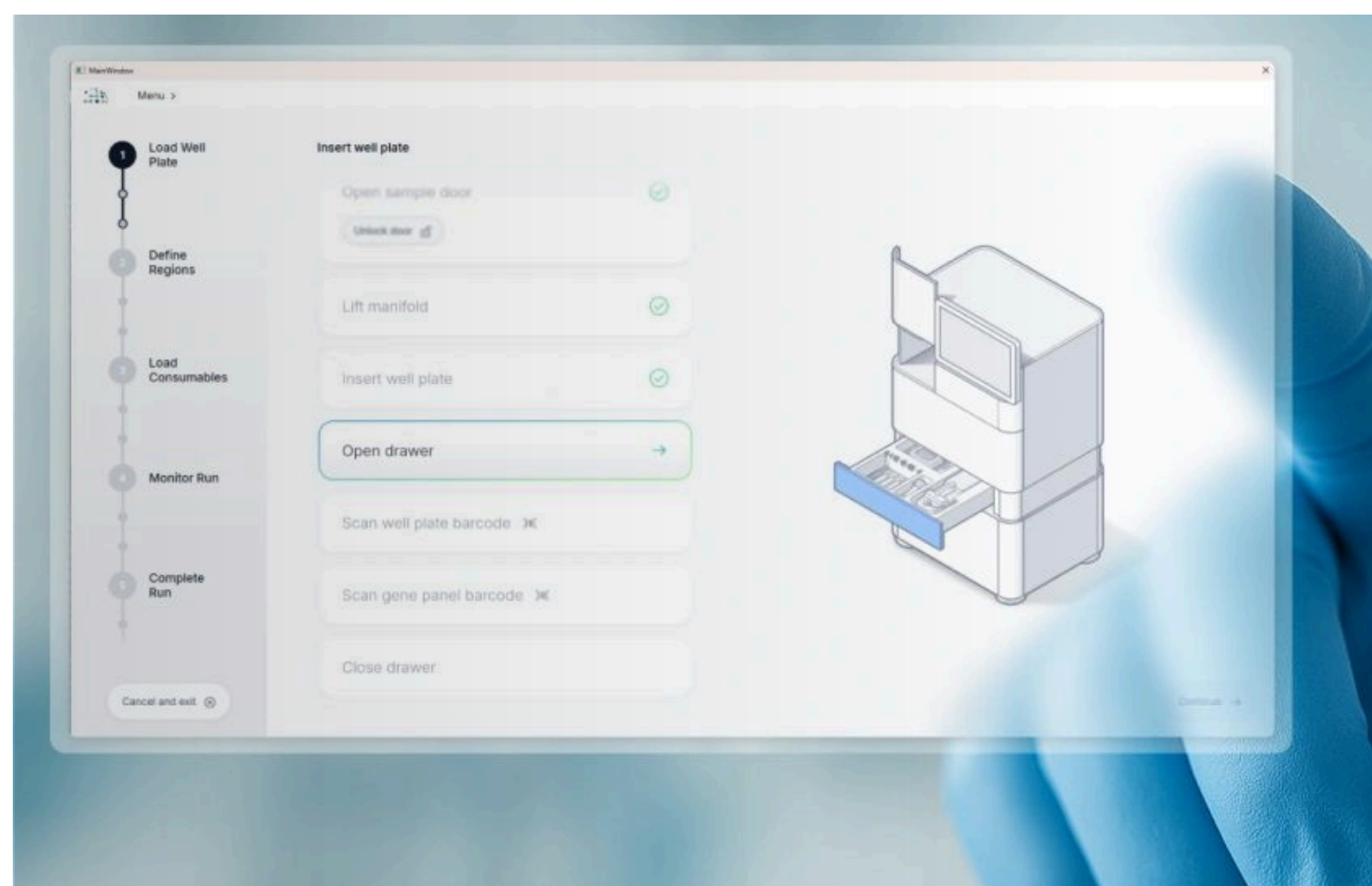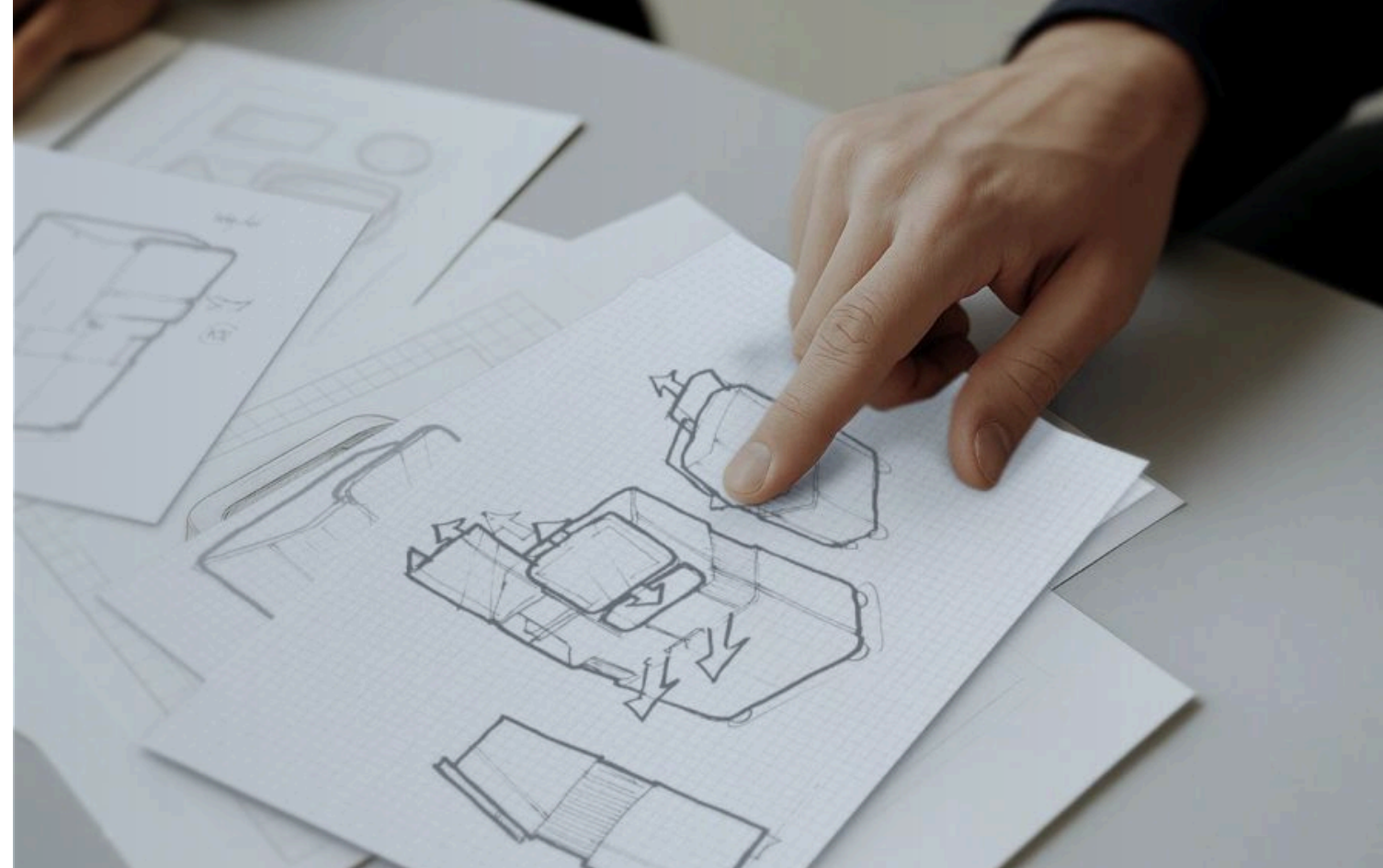
Step 5 | Prepare for Compliance and Investment

Align your design story with regulatory and business goals.

At this stage, it's about translating your design effort into credibility - for investors and regulators alike.
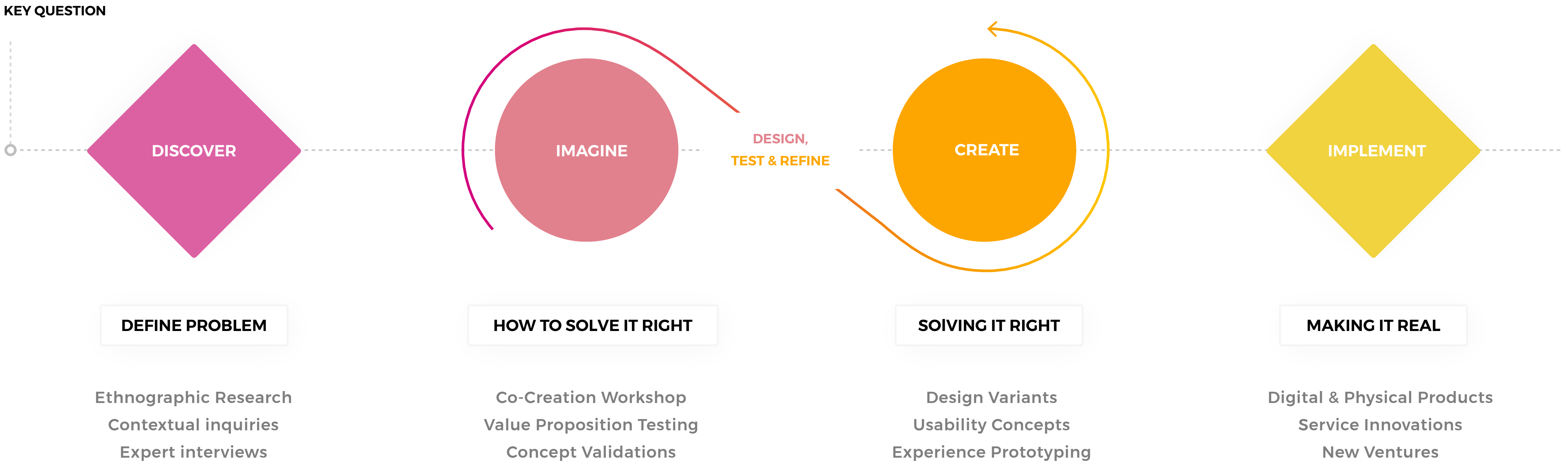You'll need both a compelling product narrative and traceable design documentation.

Key actions:

- **Capture design inputs, risk assessments, and usability data.**

- **Prepare visual materials (renders, demo videos) for investor decks.**

- **Outline your design control structure for audits or due diligence.**

- **Align with a notified body or regulatory consultant early.**

FLUID Tip:
Great design is more than aesthetics - it's your proof of rigor when facing investors or reviewers.
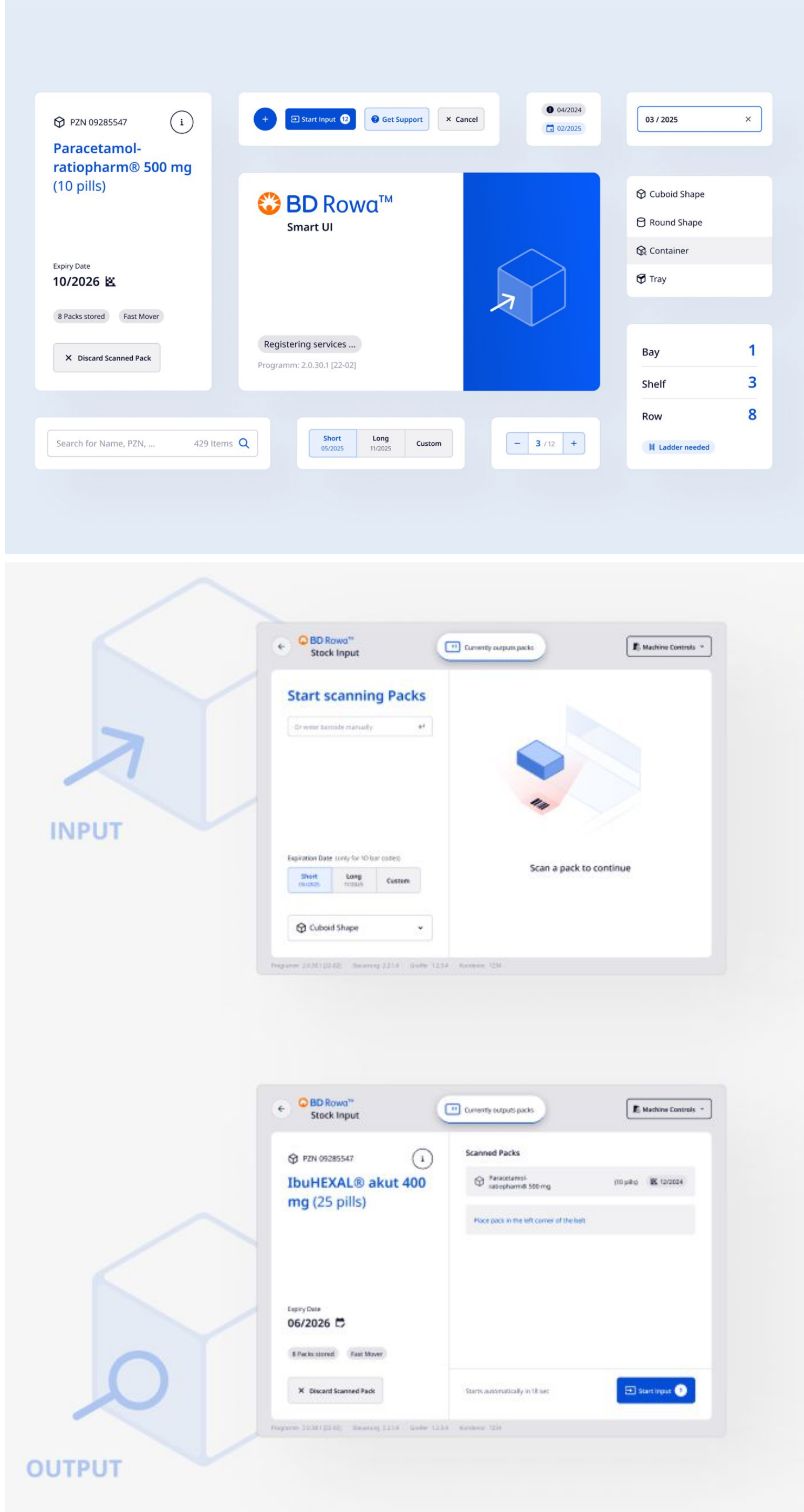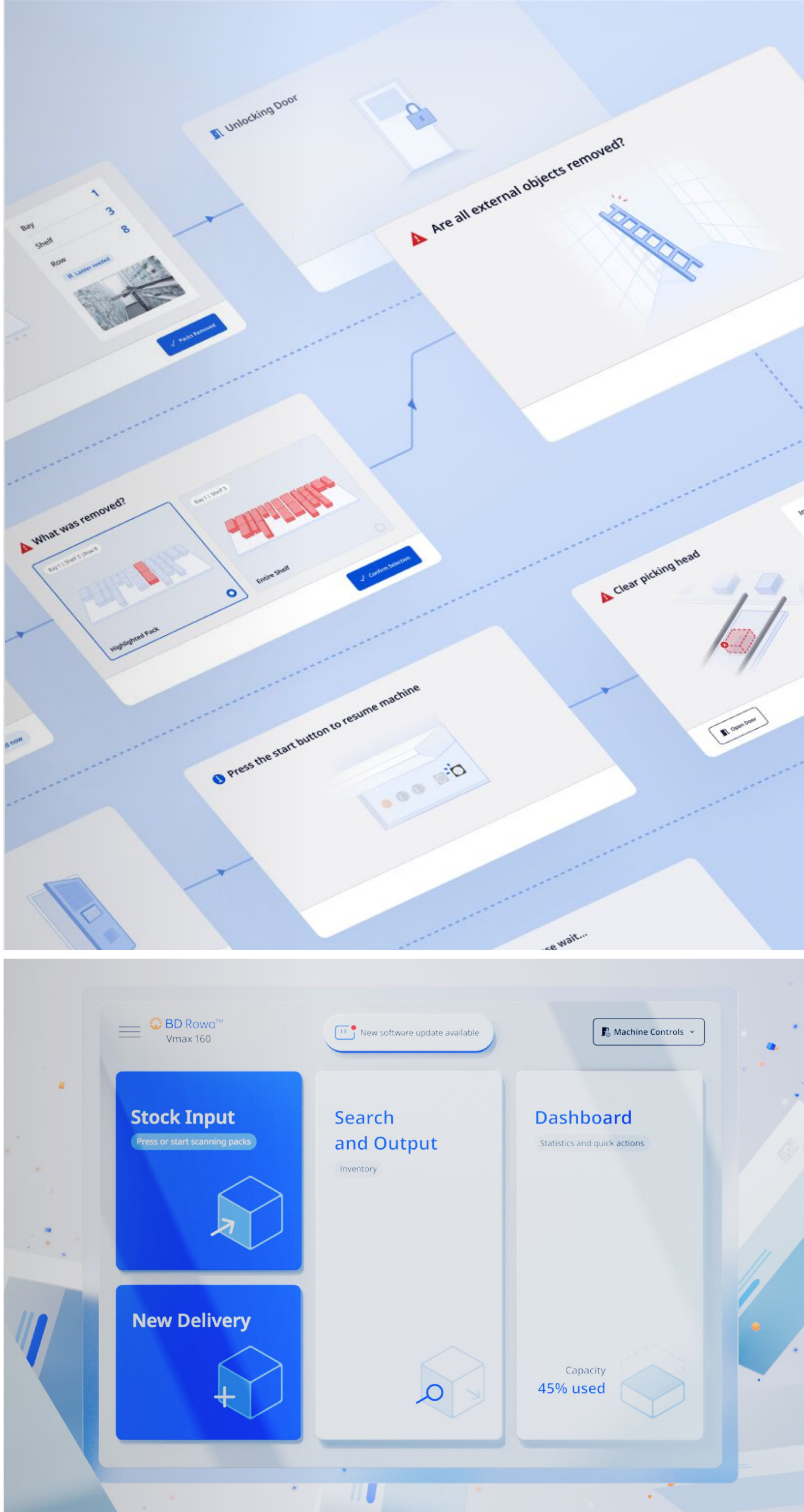
To design the right future experiences, we start by interacting with people to identify the problem that needs to be solved.

KEY QUESTION

DISCOVER

IMAGINE

DESIGN,
TEST & REFINE

CREATE

IMPLEMENT

DEFINE PROBLEM

HOW TO SOLVE IT RIGHT

SOIVING IT RIGHT

MAKING IT REAL

Ethnographic Research
Contextual inquiries
Expert interviews

Co-Creation Workshop
Value Proposition Testing
Concept Validations

Design Variants
Usability Concepts
Experience Prototyping

Digital & Physical Products
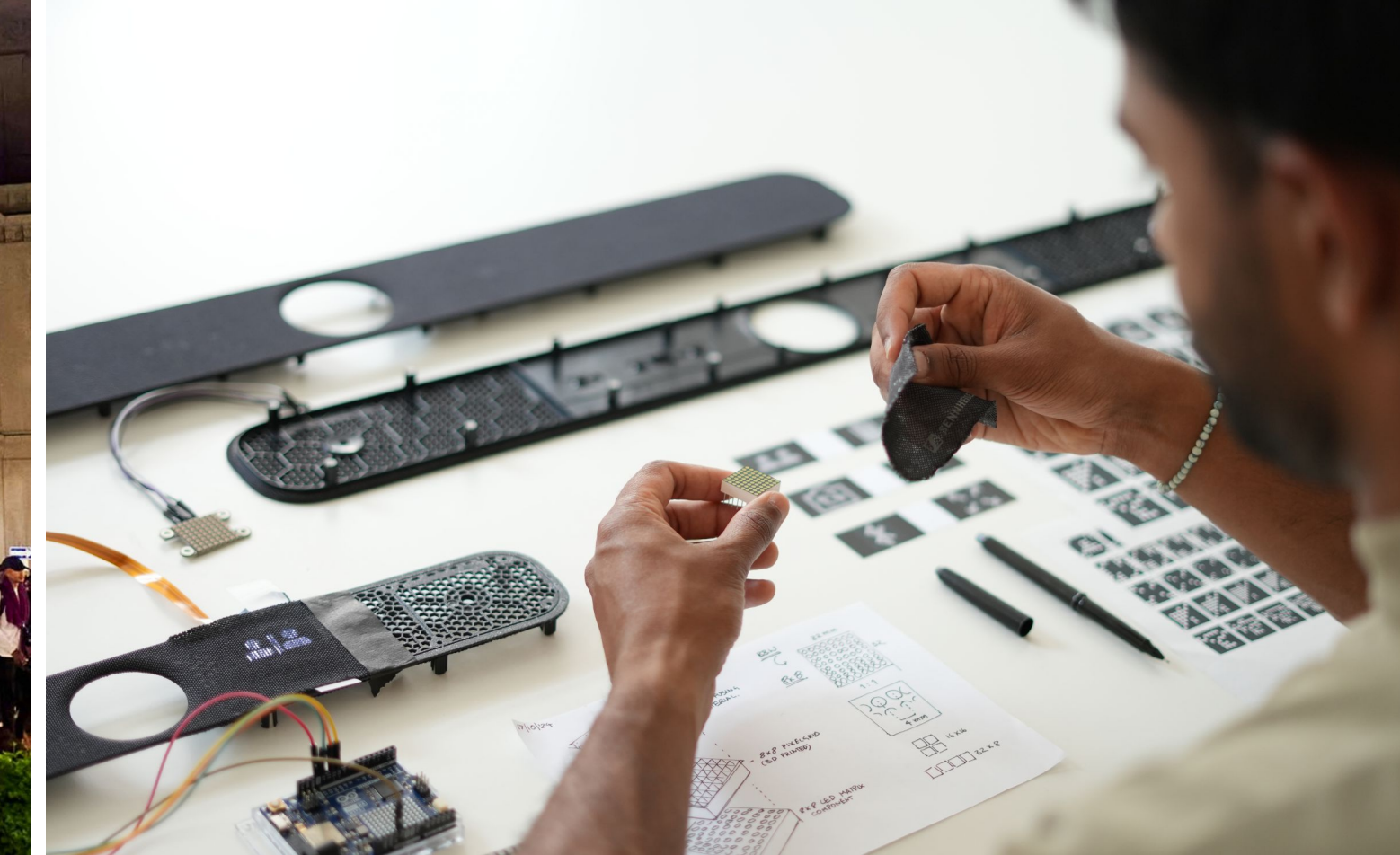Service Innovations
New Ventures

WE ARE FLUID

FLUID is an independent, international and award-winning design and innovation agency based in Munich.

We are a team of passionate creatives, researchers and strategists with diverse cultural backgrounds. Our studio is located right in the Munich city center in the vivid and creative Gärtnerplatz area.
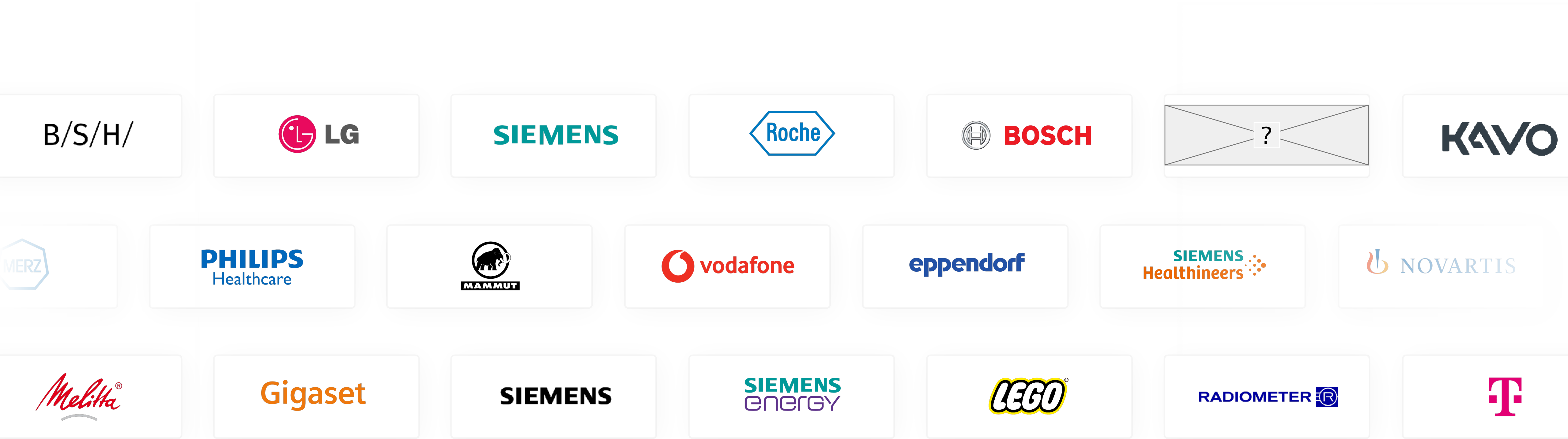
FLUID combines many years of design excellence with deep expertise in usability, ergonomics, and human-centered innovation for complex technical environments.

Our multidisciplinary team unites industrial designers, human factors specialists, UX/UI experts, and strategists, enabling us to bridge physical and digital product experiences seamlessly.

We shape organizations from early-stage startups to
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