# Legal Value Chains

# Expected impact

- Policy makers aware about the impact of new regulations on implementation of new innovations in healthcare

- A better equipped innovation support system

- Regulatory readiness among startups, clinicians, and academics

Which leads to:

- More medtech innovations reaching healthcare and patients in need

- More successful medtech companies and research projects in the region/nationally

- More jobs in the sector

# Healthcare innovation – the context

# Changing macro environment

- MDR 2021

- IVDR 2022 or? Similar to MDR but an even bigger leap

- CTR – new EU law on harmonizing clinical trials for pharma products

- New EU law on AI - healthcare use in highest risk category

- New EU law on health technology assessment

- Standards and guidelines renewed continuously e.g.

- ISO standard for health and wellness apps **ISO/TS 82304-2:2021**
- …

- Law on company secrets (Företagshemlighetslagen)
- ABAC/Samverkansreglerna
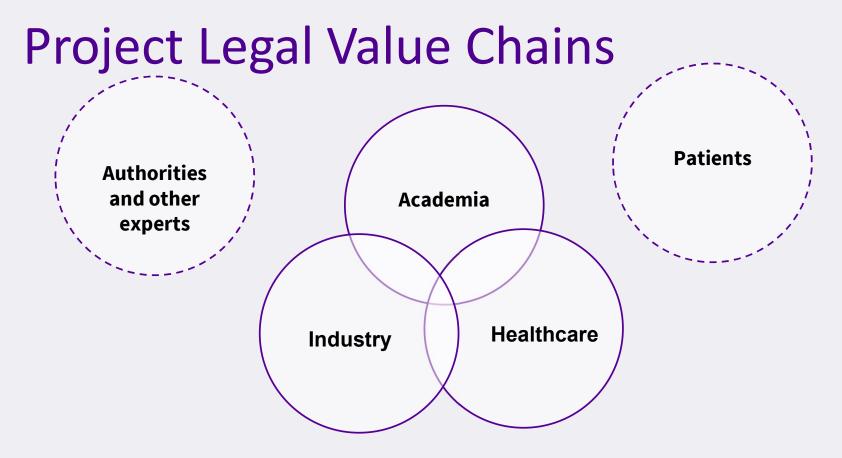- Whistleblower requirements
- Stadsstödsregler

# Healthcare innovation 4.0



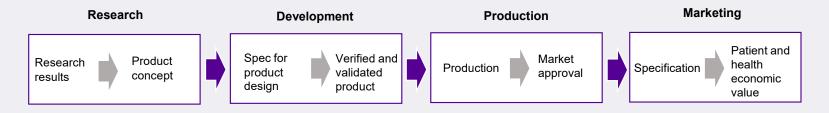What if we could combine legal awareness/compliance with intellectual assets mapping?

# Project Legal Value Chains

Authorities and other experts

Academia

Patients

Industry

Healthcare

Focus is research and innovation in this mixed context.

# The process

We evaluate and and describe WHAT is needed  WHEN in a research and innovation project in terms of regulatory and compliance

**Research**

| Research results | → | Product concept |
|---|---|---|

**Development**

| Spec for product design | → | Verified and validated product |
|---|---|---|

**Production**

| Production | → | Market approval |
|---|---|---|

**Marketing**

| Specification | → | Patient and health economic value |
|---|---|---|

Task 1 – Develop product concept and the project resource base

Task 2 – Establish and position the research and innovation project

Task 3 – Organise and establish processes to drive the research and innovation project

Task 4 – Develop value offerings for healthcare and patients

Taks 5 – Enable policy development, changed routines and ways of working

# Fictive case

- Hardware, software and personal/patient data

- A new fruitful combination of known technologies

- Status: About to start a company

- Stakeholders in academia, healthcare as well as industry (small and big)

- National and foreign stakeholders

- Turnover; people both leaving and joining

- IOW, the "usual entrepreneurial mess"

# Project Deliverables

- Training materials - focus MDR and data privacy
- Written report
- Landing zone together with other M4H initiatives

# Intellectual Assets Mapping rev 2

| | Type | Who/How? | Weight (1-5) | Control | Action |
|---|---|---|---|---|---|
| IA1 | Database | Uni | 3 | Research license only | Renegotiate terms |
| IA2 | Raw material spec | Arne X | 3 | Supply agreement expiring 2022 | Renew agreement |
| IA3 | Analytic software | Lars Y | 4 | No consultancy agr w Lars Y | Regulate customer use, check ownership |
| IA4 | Sensor coating method | Arne X | 4 | Patent pending | File additional conutries/regions |
| IA5 | Product name | Branding agency | 2 | Trademark in Sweden | File CTM, US and CN |
| IA6-15 | Technical file | Consultancy/in house? | 5 | Contract | Internalise, keep confidential? |
| IA16-20 | Clinical plan/data | Lisa Z | 4 | Study agreements, CRO | |