Einkauf & Logistik

Medical Device Regulation – curse or blessing?

Perspective of a hospital

Philippe Linder, Head of Procurement & Logistics
19 October 2022

MDR – the perspective matters

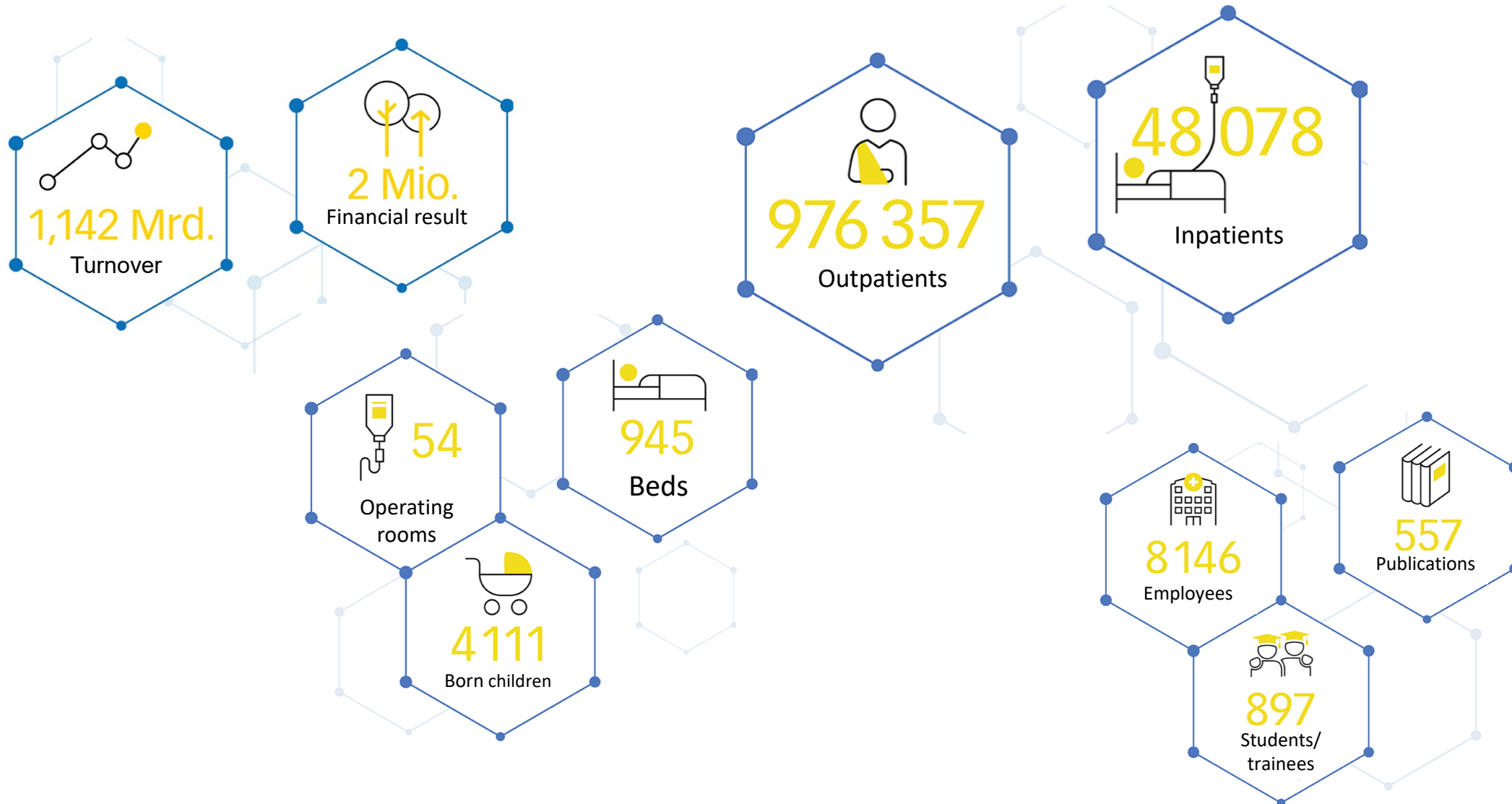How do I grasp the current situation with the necessary foresight?

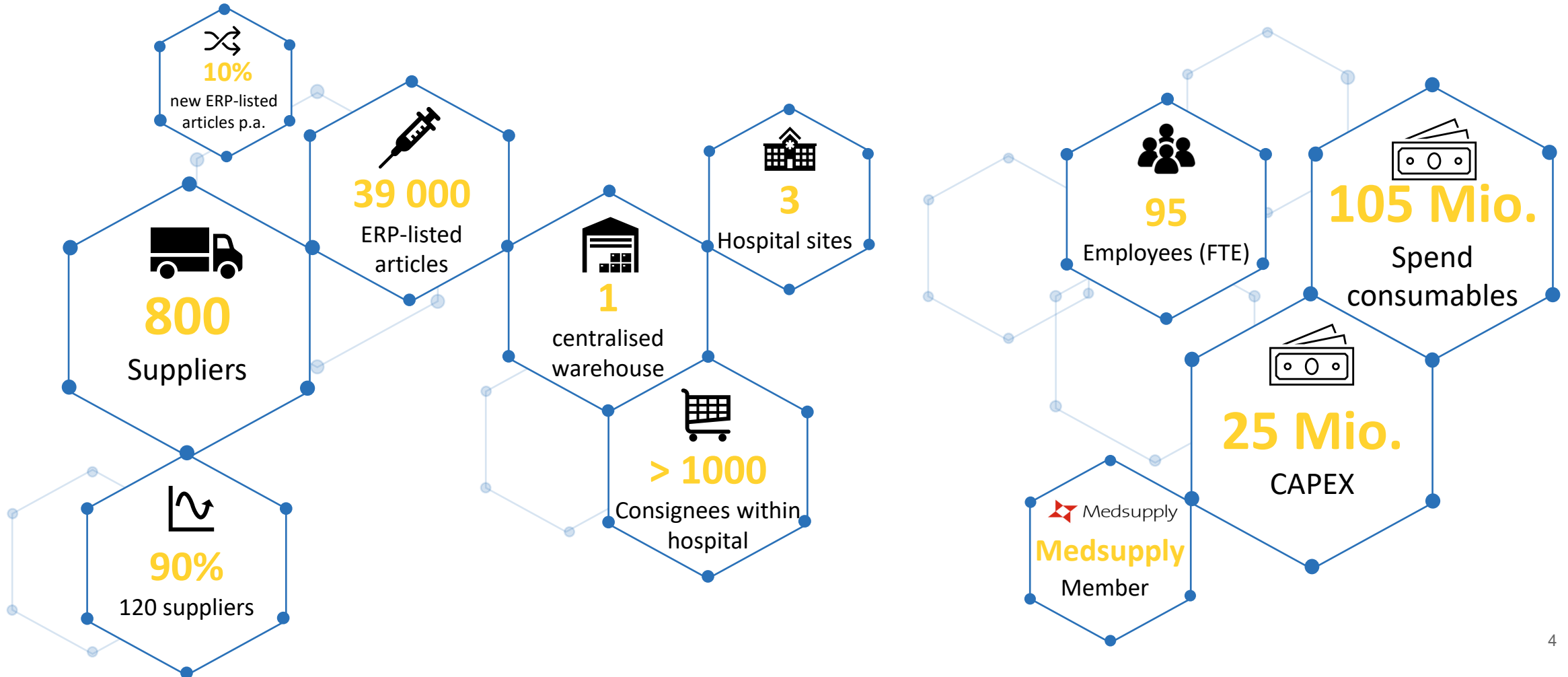

View up direction «Schwanderfluh»

View down from «Schwanderfluh»

LUKS Group in Figures (2021)

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1,142 Mrd.
Turnover

2 Mio.
Financial result

976 357
Outpatients

48 078
Inpatients

54
Operating rooms

945
Beds

4 111
Born children

8 146
Employees

557
Publications

897
Students/ trainees

Facts and Figures Procurement & Logistics 2022

One stop shop for all hospital sites

- **10%** new ERP-listed articles p.a.
- **800** Suppliers
- **39 000** ERP-listed articles
- **90%** 120 suppliers
- **1** centralised warehouse
- **3** Hospital sites
- **> 1000** Consignees within hospital
- **95** Employees (FTE)
- **105 Mio.** Spend consumables
- **25 Mio.** CAPEX
- **Medsupply** Member

MDR is now reality – but what does this mean, exactly?

No MRA with the EU - database which does not work/is not yet accessible

- Revision of the Medical Devices Ordinance (MedDO)
- Changing timeline: MDD (92/42 EWG) to MDR (2017/ 745)
- New economic actors within the meaning of the legislation
- Regulatory requirements leave room for interpretation/are vague
- E.g. Article 65, paragraph 1 MedDO:

«the healthcare institutions record and store, preferarbly electronically, the UDI of class III implantable devices they have received or dispensed

➡ Information from the UDI is already recorded as part of the medical documentation in the Clinical Information System (Krankenhausinformationssystem (KIS))
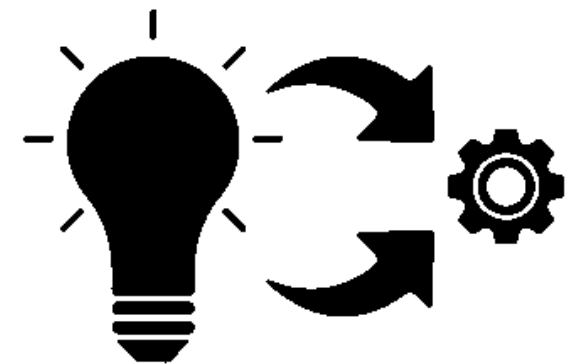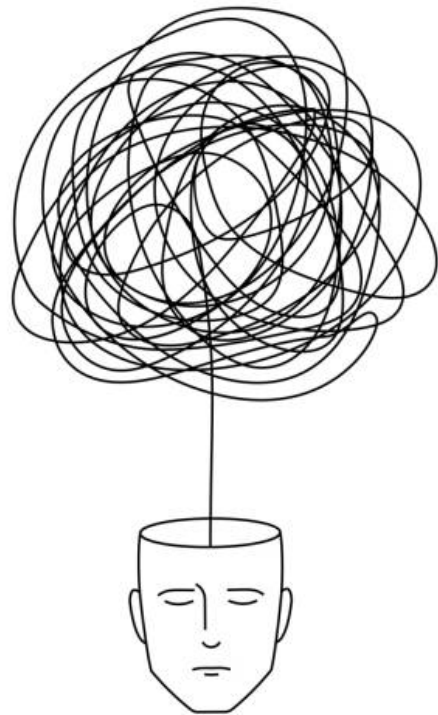
Product Labeling

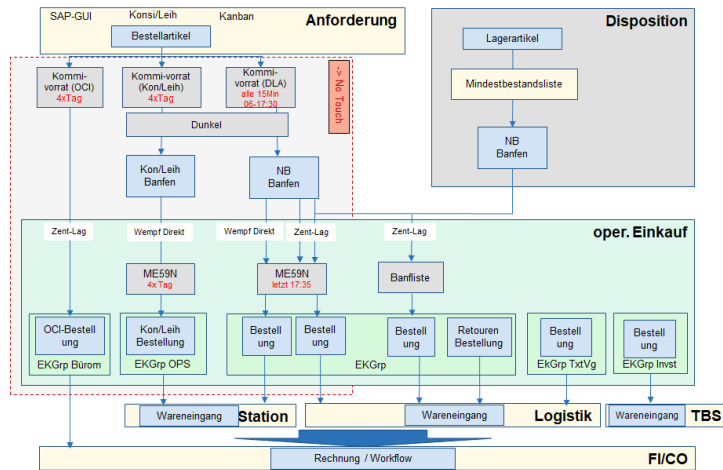**Also without MDR/missing MRA for certain economic actors a headache**

CHRN
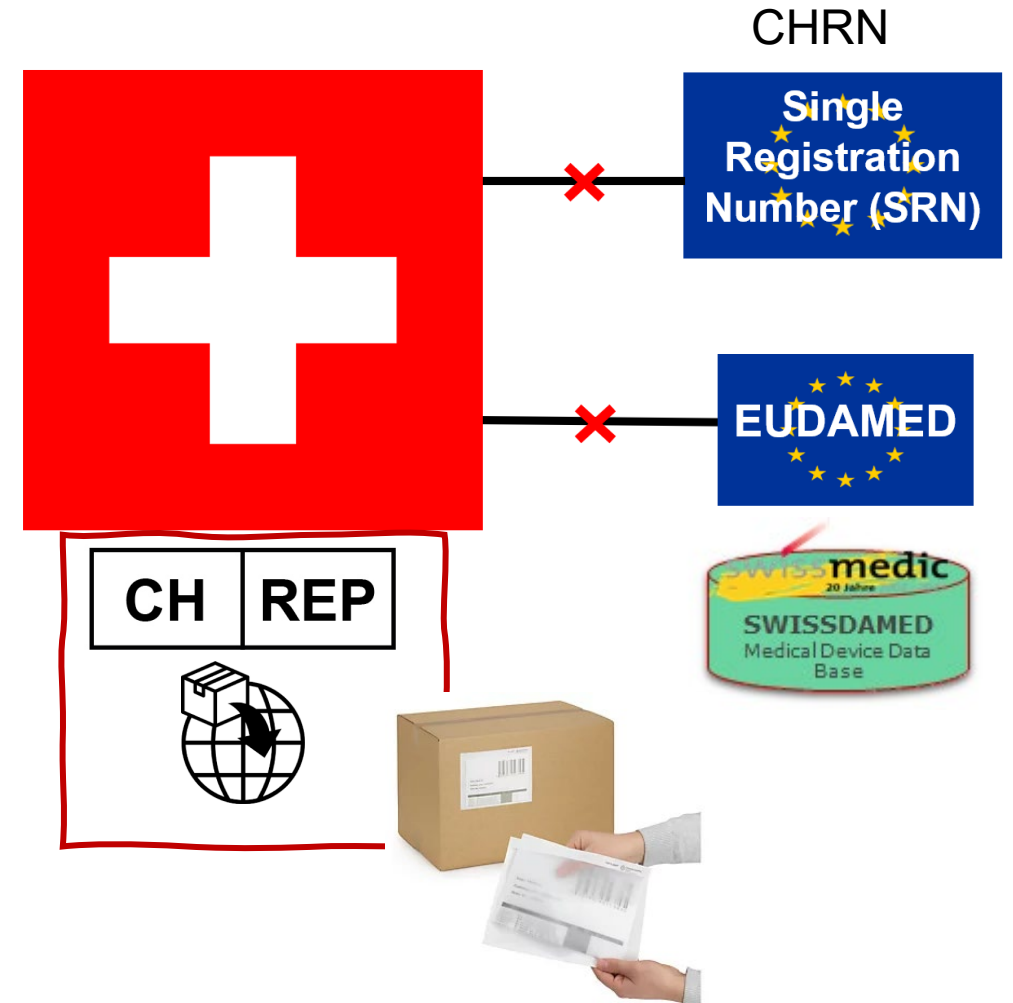
If unclarity prevails, the devil takes the hindmost

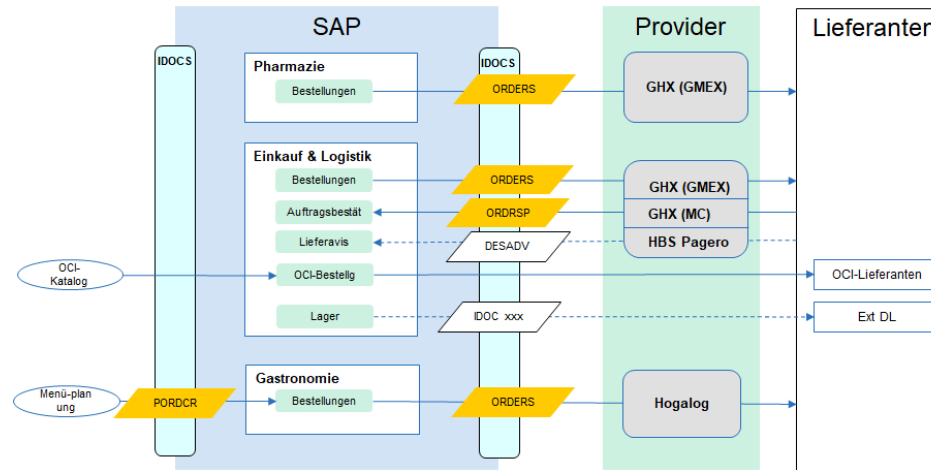**Clear structures/ processes which are not only enforced but also lived by the individuals**
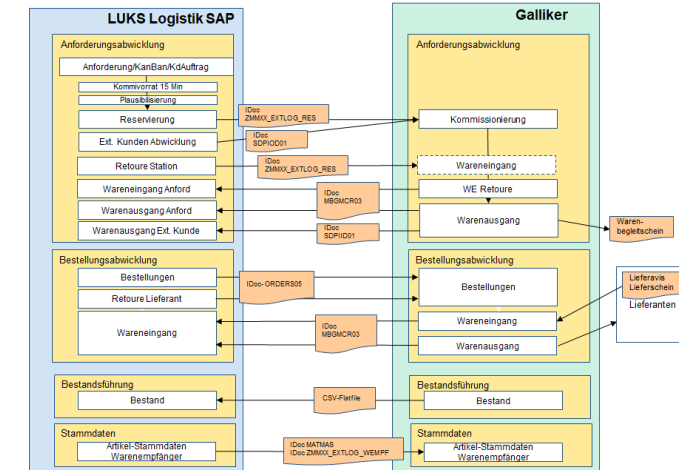
Our «engine» in procurement is SAP

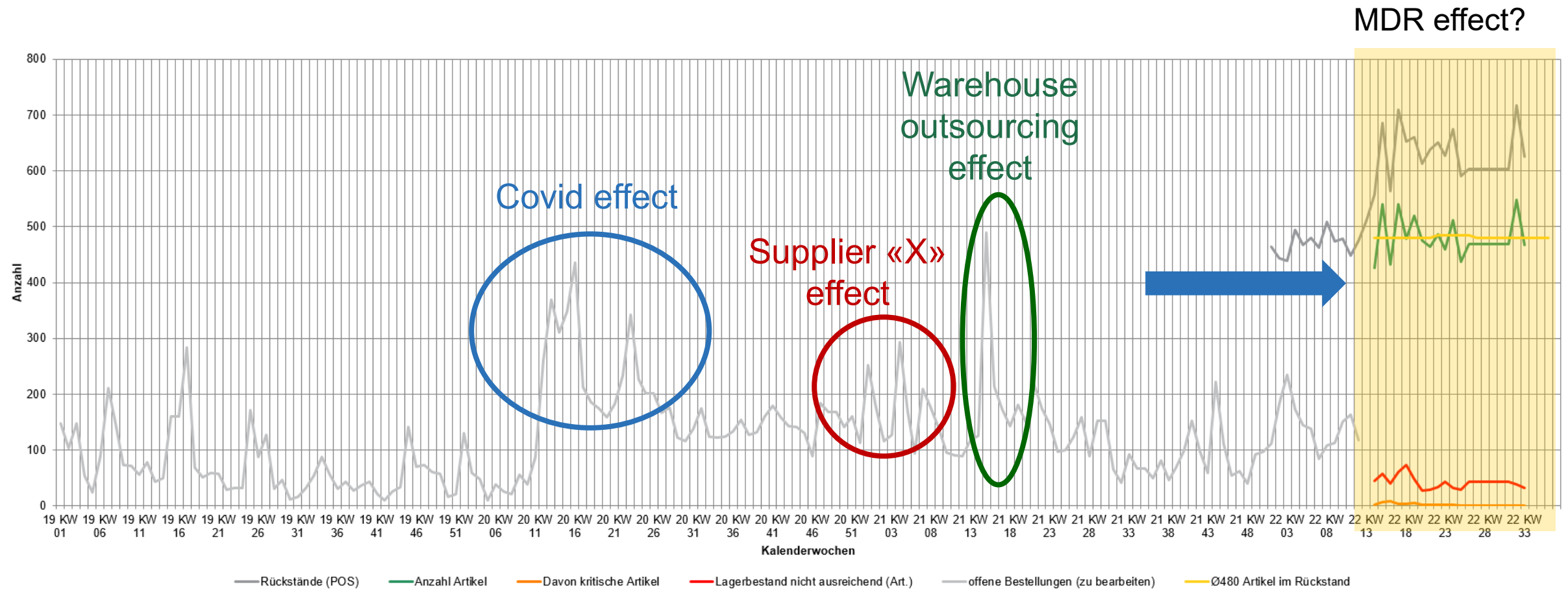**Backbone for a high quality Supply Chain**

MM, SD & APM

EDI interfaces

Scare, **A**ngst and **P**anic

Backlogs Management

Transparency which needs to be passed on to internal stakeholders – namely doctors and nurses

How do we get a handle on MDR «system-wise»?

Objective: simple tool in SAP

- Assign the following date per article in SAP:
  - Product class
  - Certificate data (Manufacturer, number, type, Notified Body, validity, etc.)
  - UDI
- Certificates are stored in a *structured* way and not as a document
- Data shall be available from
  - EUDAMED or
  - Be queried/ imported from a Swiss-specific database
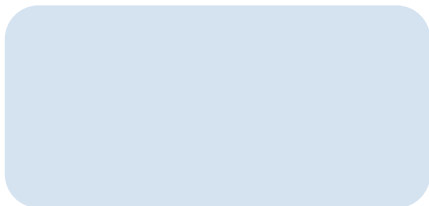- Temporary solution: Export data via csv. File and re-import again (mass upload)

Implementation in SAP – Data Model

The MDR tool from Snap Consult is used*

Material master

- Product class
- UDI (GTIN)

Equipments

Link (technical)

«Table» in MDR Tool

Certificates

- Certificate number
- Certificate type
- Valid from … to …
- Notified Body
- Manufacturer
- Document annex
- …

* https://www.snapconsult.com/snapware-smarte-softwareloesungen-fuer-wertvolle-sap-prozesse/snapware-healthcare/mdr-zertifikatsverwaltung-im-schnelldurchlauf

Implementation SAP – «Views»

View master data

Interaction of the stakeholders

SNAP MDR Tool – one «central database»

LUKS

«Economic actors»

Potential «suppliers»

Article list LUKS

SAP

Article list LUKS supplemented by:
- Product class
- Certificate data

<ERP>

<ERP>

<ERP>

<ERP>
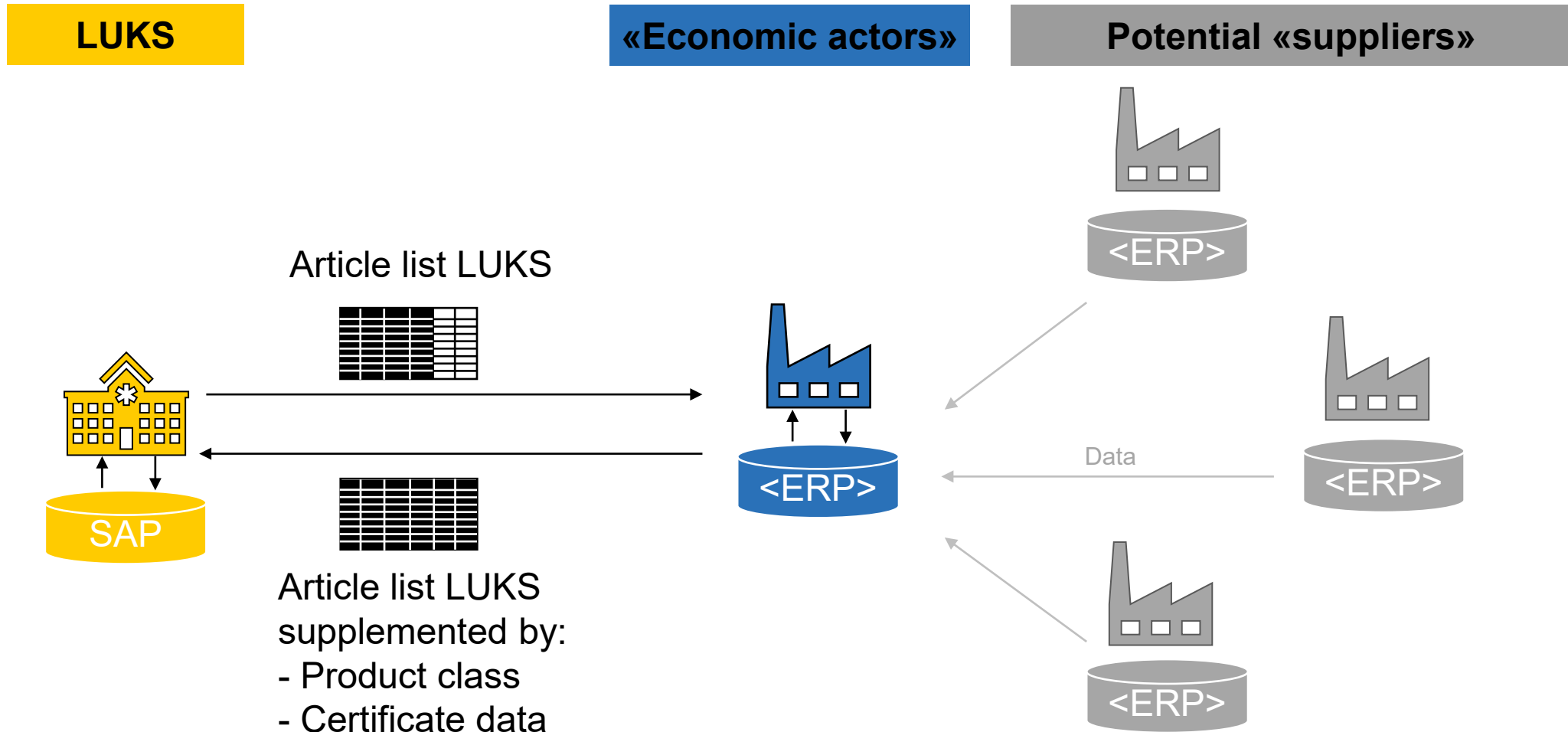
Data

Connection to central database» – dreams of the future?

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Direct connection possible with MDR tool

LUKS

«Economic actors»

Potential «suppliers»

<EUDAMED>

<GDSN Pool>

«DI»
(GTIN)

Certificate
data

SAP

Data

<ERP>

<ERP>

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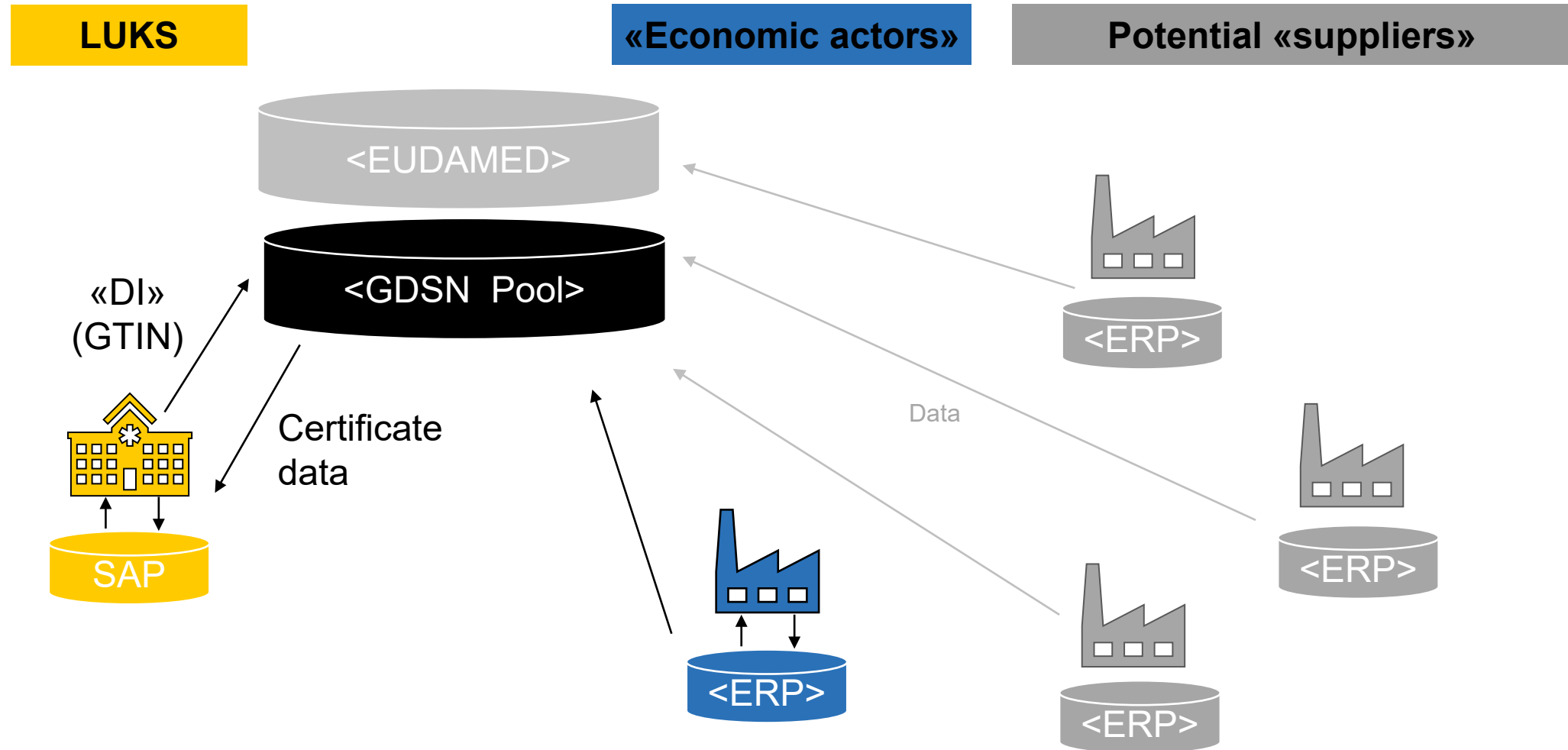
«firstbase»* – one «master data truht»

Powered by GS1

* https://www.gs1.ch/de/aktuelles/innovation/neue-datenaustauschplattform
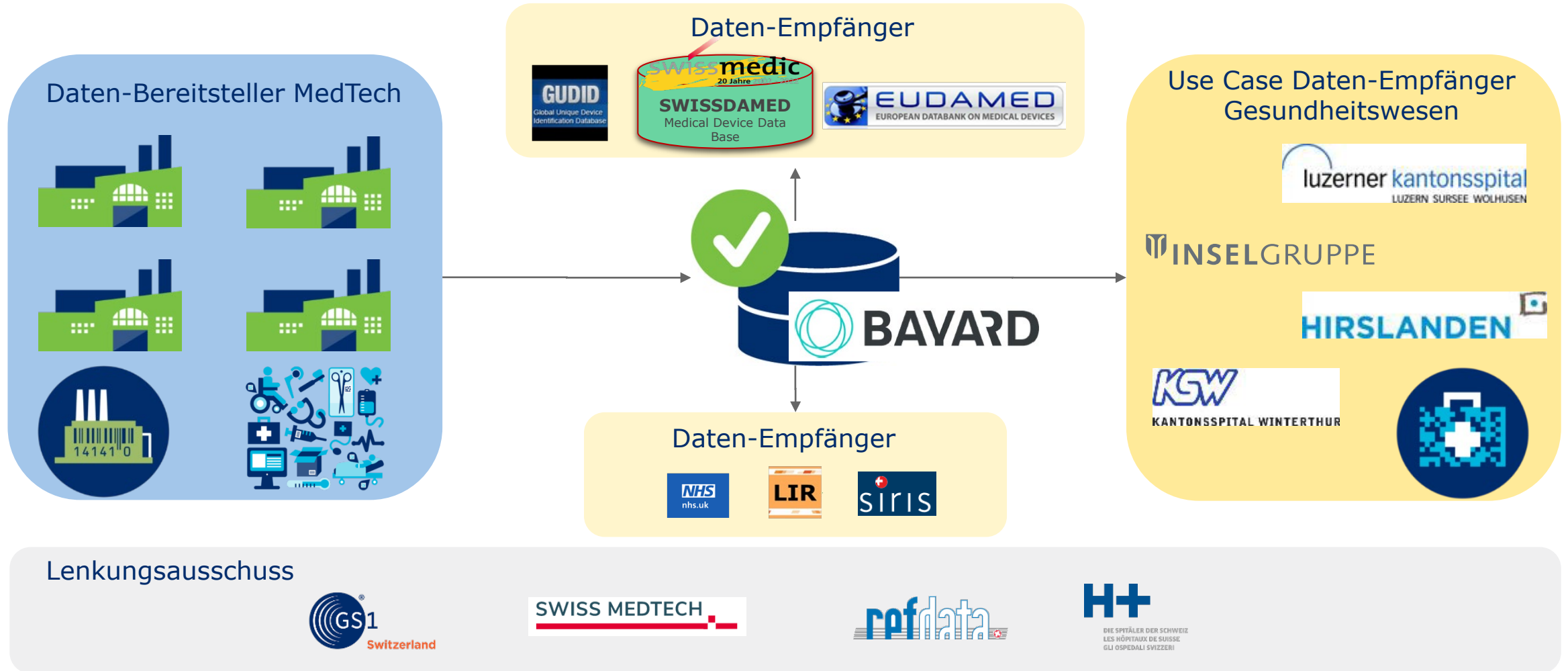
Partnerships with suppliers are essential

MDR requires end-to-end systems/ knowledge more than ever – the gap is huge

- we expect knowledge & data on the current MDD/ MDR situation
- Contemporary IT systems
  - Interconnected systems
  - Master data that also deserve the name
  - EDI (GS1 Standards)
- Communication
  - transparent – delivery dates
  - proactive – act in the event of emerging problems
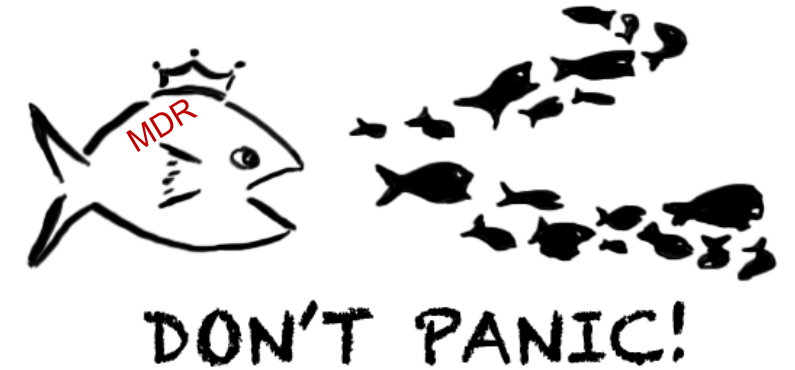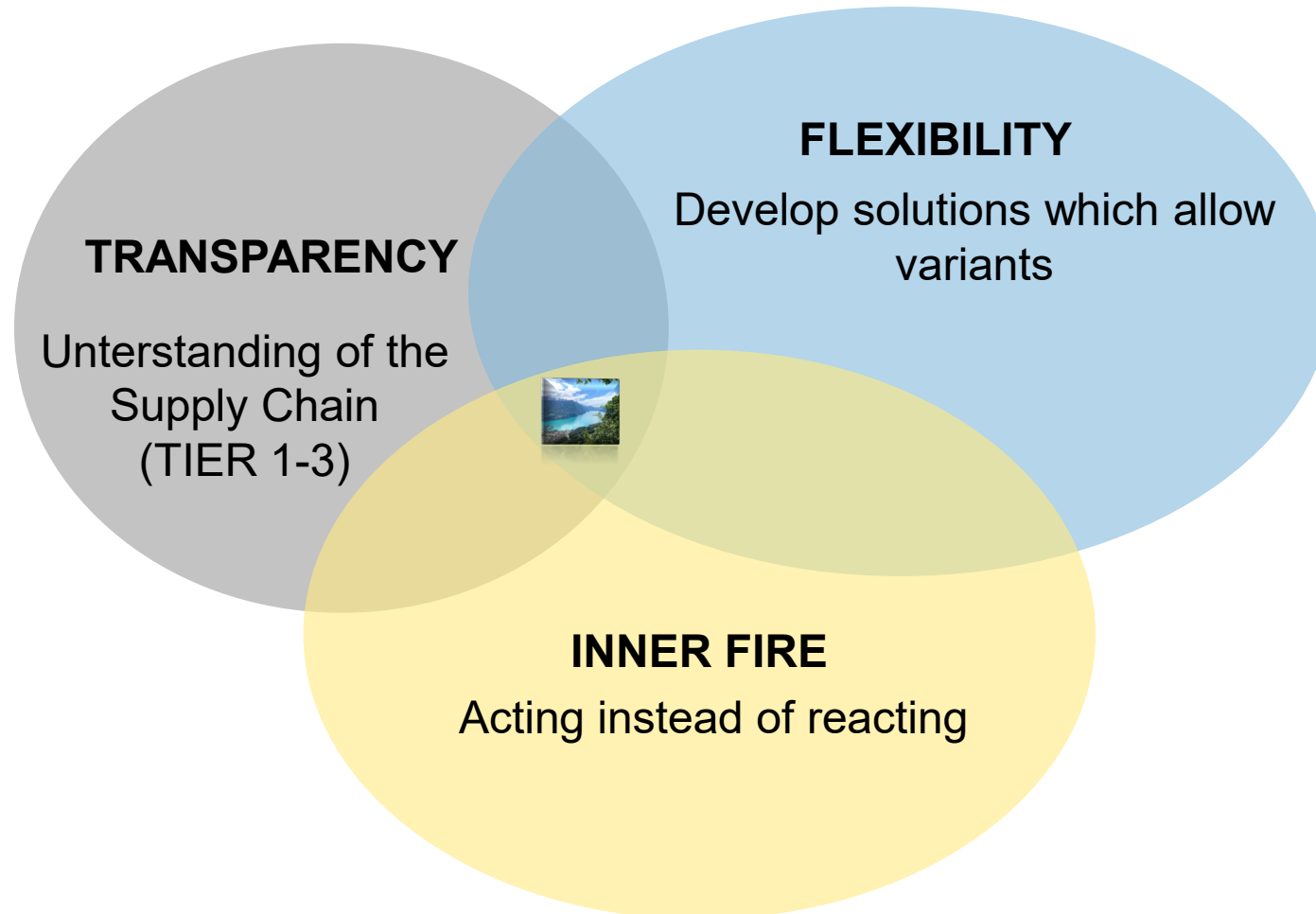 - competent – where/how is supplier positioned
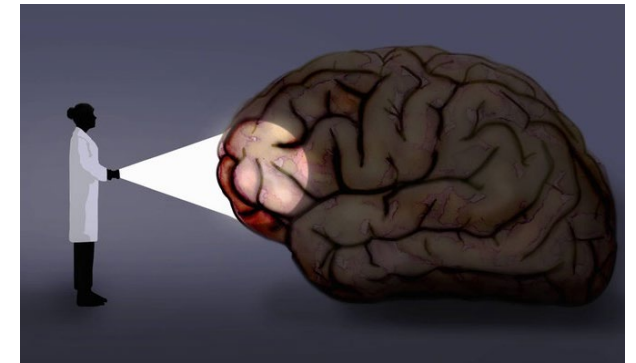
Lessons learned

MDR as a «fire accelarant» for a long overdue step change

- Adjusting «systems» to a new reality
  - more know-how – Suppliers & hospitals
  - IT/ Applications
- «Supply» is changing
  - Streamlined supplier portfolio
  - Streamlined product portfolio
- «Visibility» of products
  - Label (Standards)
  - Traceability
  - Better master data

«Target agility» is needed

WANTING what you CAN and MAY do

FLEXIBILITY

Develop solutions which allow variants

TRANSPARENCY

Unterstanding of the Supply Chain (TIER 1-3)

INNER FIRE

Acting instead of reacting

Thank you for your attention

Questions?

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