


# **International Horizon Scanning Initiative**

## 2. The database

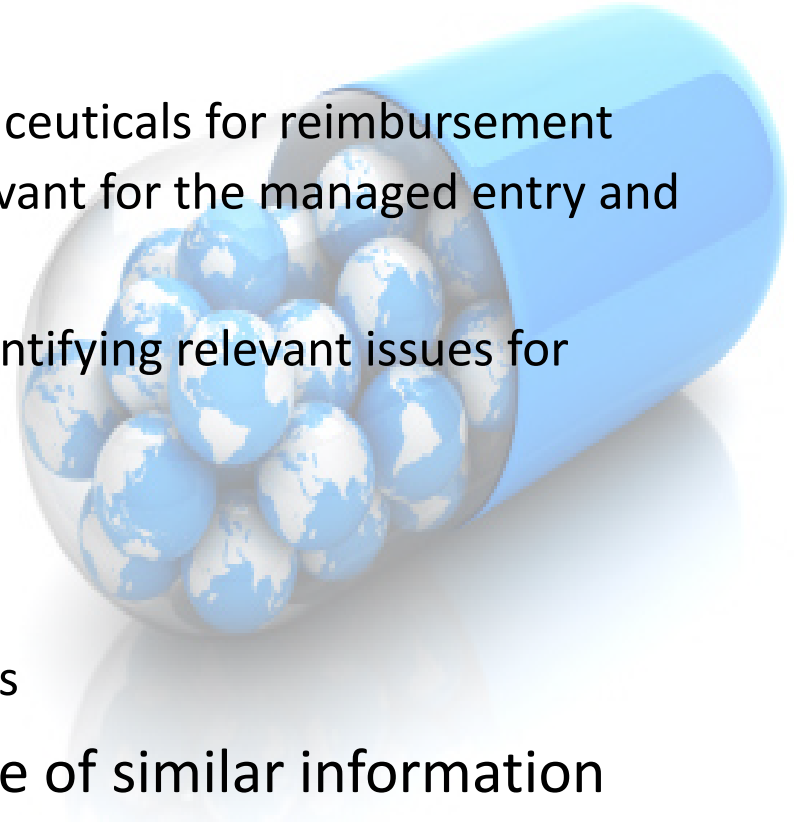


*"A pessimist sees the  
difficulty in every  
opportunity; an optimist sees  
the opportunity in every  
difficulty."*

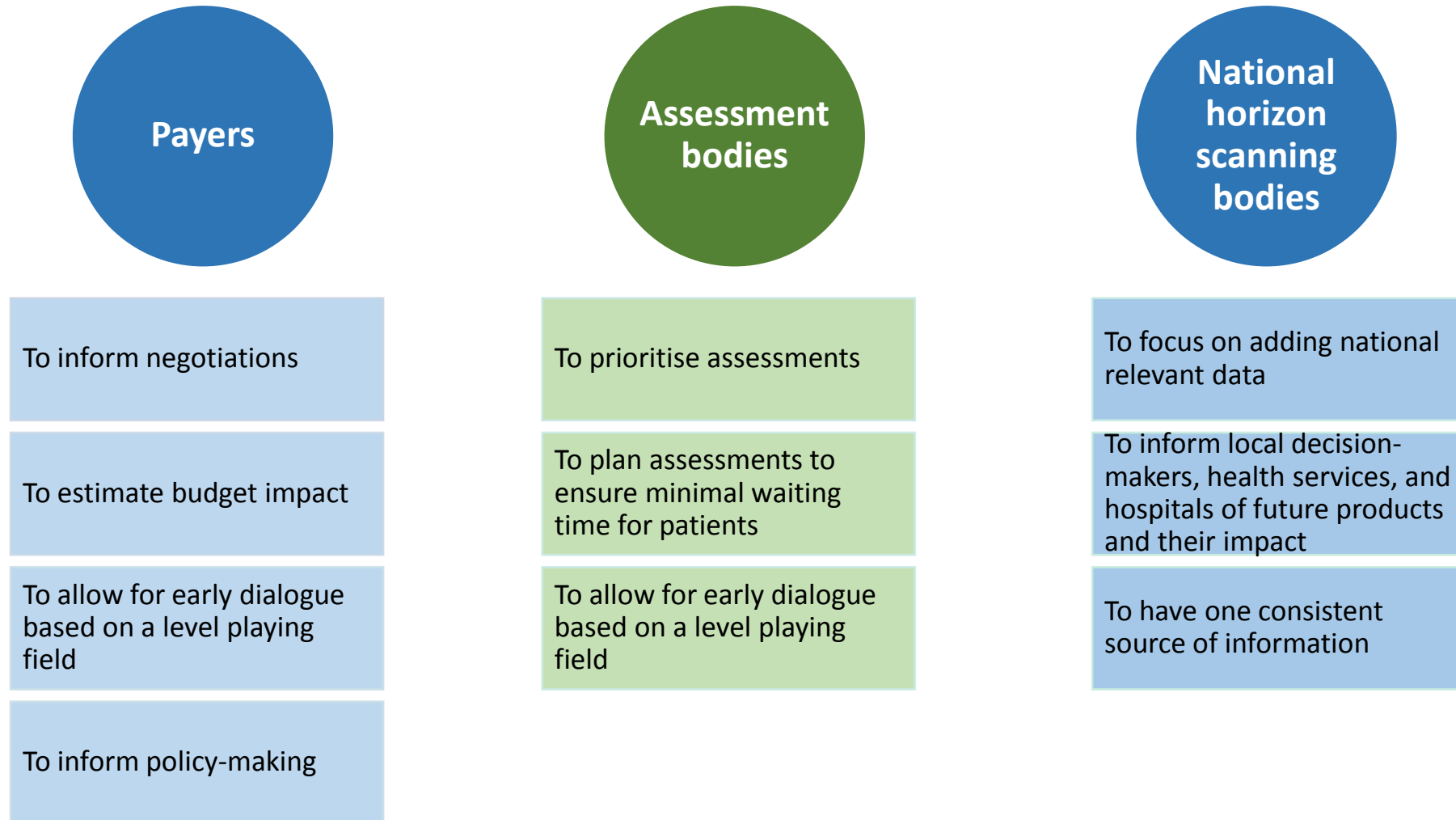
**Winston Churchill**

# International Horizon Scanning Initiative (IHSI)

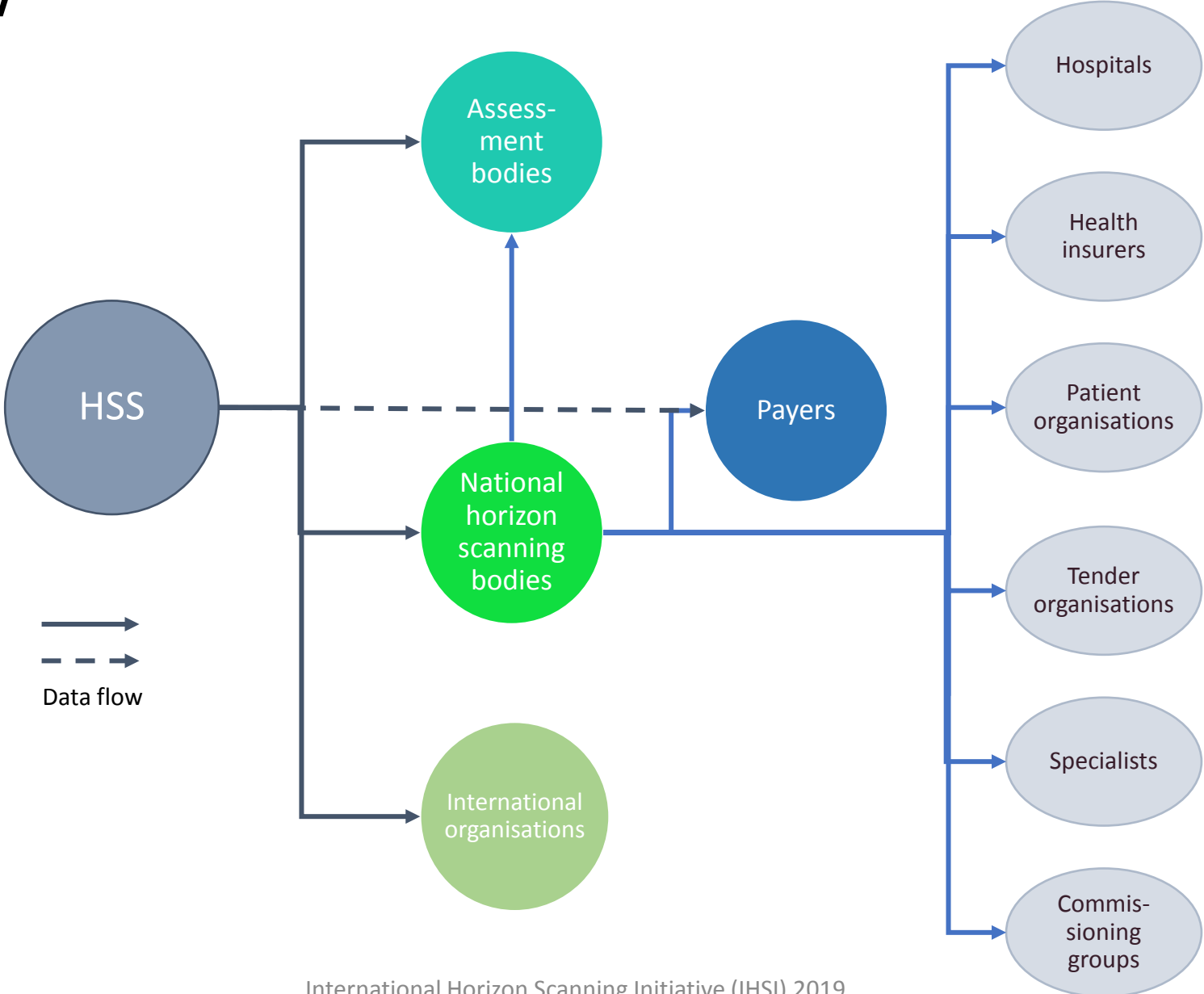
- ▶ Aim of a joint HSS:
  - ▶ To inform decision-makers on emerging and new pharmaceuticals for reimbursement decisions and policy development on issues that are relevant for the managed entry and monitoring of new products
  - ▶ To enhance collaboration between member states by identifying relevant issues for collaboration
  - ▶ To level the playing field
  - ▶ To enable prioritisation according to potential impact
  - ▶ To allow for early dialogue between relevant stakeholders
- ▶ Countries see potential in working together because of similar information needs and thus central data collection (HSS)



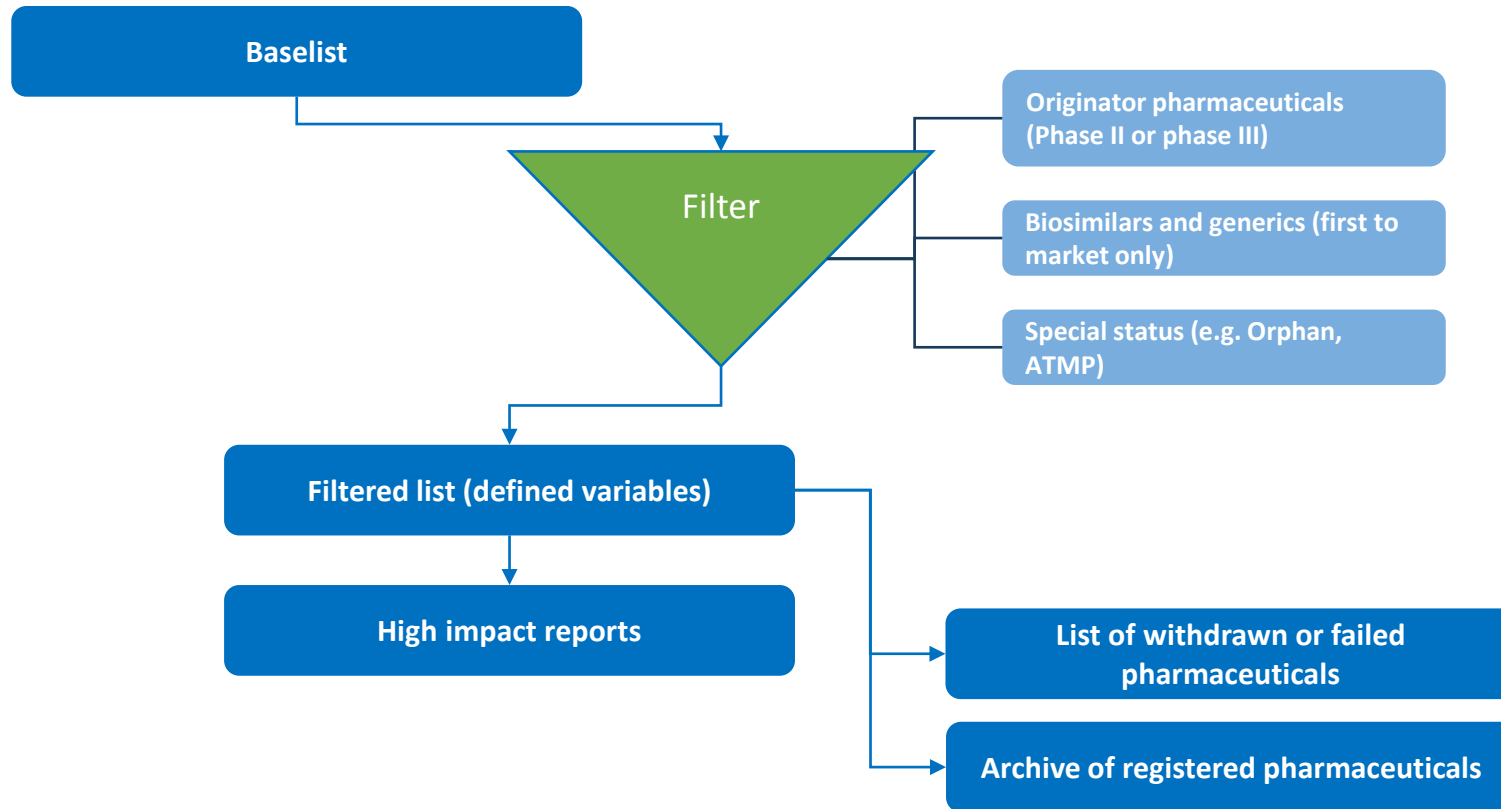
# End-users and how they use the data



# Data flow



# Proposal for a database



*“HSS aims at **identifying**, **filtering**, and **prioritising** new and emerging health technologies with a considerable predicted impact on health, costs, society and the health care system in order to inform policymakers, purchasers, and health care providers or facilitate early access”* (KCE report 2017)

# Baselist and filtered list

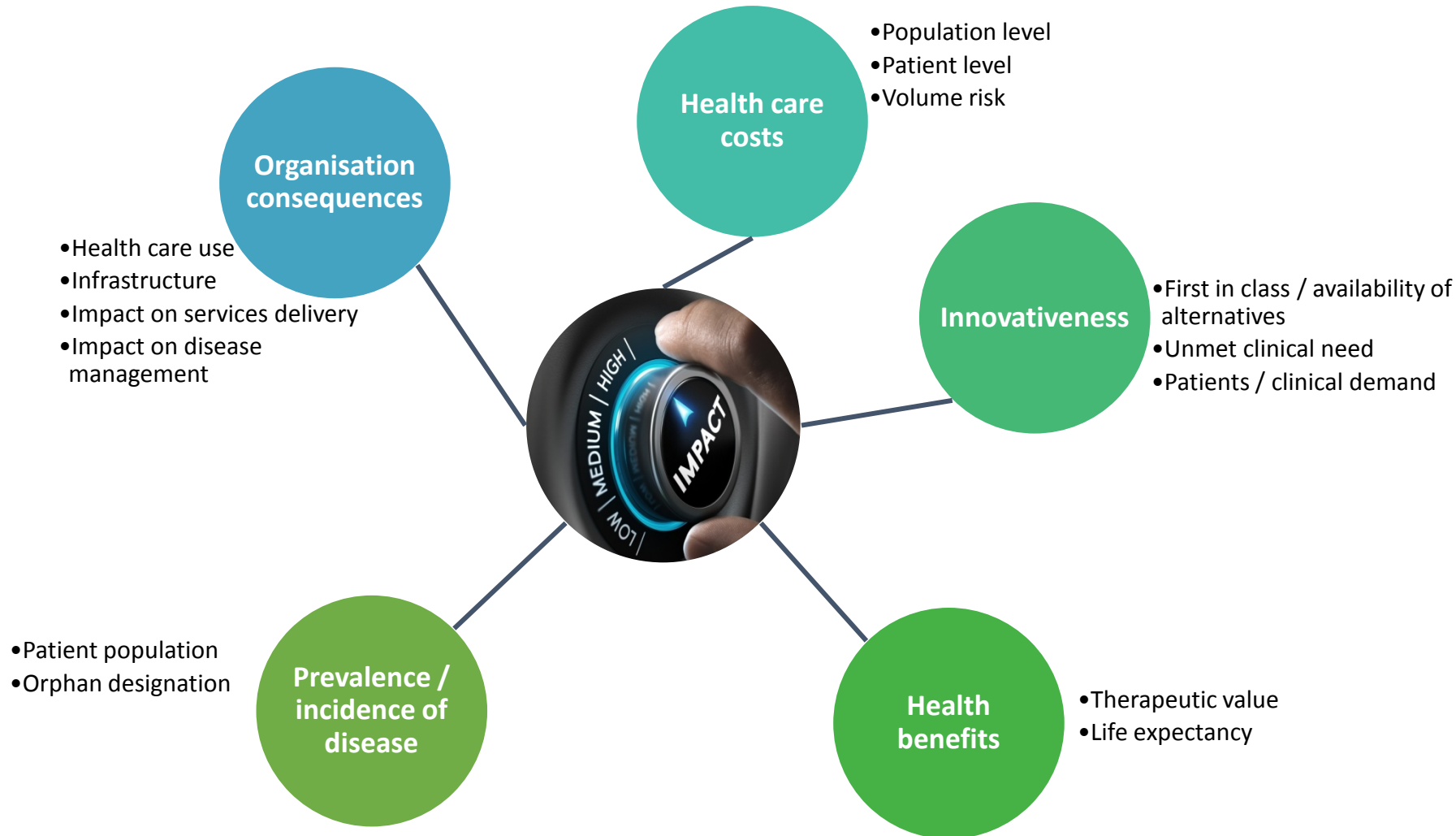
- ▶ Baselist: a list of pharmaceuticals in development
  - ▶ Aim: to provide insights in the industry pipeline and to enable insights into possible gaps of research
  - ▶ From early phase one for pharmaceuticals with limited data collection
  - ▶ Aligns with the European clinical trial register
- ▶ Dataset 2: a filtered list with
  - ▶ Aim: to provide insights into products expected in the short-run
  - ▶ An overview of all originator pharmaceutical products in development from phase II / phase III and
  - ▶ Also includes first to enter biosimilar and generics and pharmaceuticals with a special status
  - ▶ Data is public data
- ▶ Database includes tracking of withdrawn or failed products
- ▶ Database includes keeping the information on registered products available, however without updates



# High impact reports

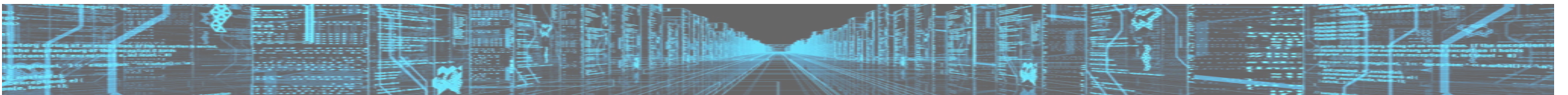
- ▶ Enables prioritisation
- ▶ Scientific method to determine high impact
- ▶ Requires a network of KOLs for assessing the potential impact on upcoming products
  - ▶ Minimum of ten disease areas
  - ▶ Minimum of 5 years of relevant experience as medical specialist
  - ▶ Policy for conflict of interest
  - ▶ Aim to publish KOL list
- ▶ Reports published twice a year
  - ▶ Intention to publish these to the general public

# Proposed parameters for high impact



# Data sources

- ▶ Data needs to open or can be made public
- ▶ Data always needs to be referenced to appropriate sources
- ▶ Data collection can be (partly) automated with prior approved algorithms
- ▶ Following sources are relevant:
  - ▶ Registries of clinical data
  - ▶ Regulatory authorities including FDA and EMA
  - ▶ Scientific reports and journals
  - ▶ Input from clinical experts
- ▶ The role of potential input from industry is to be decided on by IHSI members



# Variables

- ▶ The tender will include a list of variables that need to be included in the database
- ▶ These can roughly be divided into:
  - ▶ Clinical variables: relevant clinical data on pharmaceuticals and medical technologies, e.g.:
    - ▶ Trial data
    - ▶ Comparator products
  - ▶ Timeline data: data relevant to tracking to where products are in their development trajectory
  - ▶ Cost data: data related to the costs and pricing of the product
  - ▶ Data related to the disease area, e.g.:
    - ▶ Prevalence and incidence data, and other relevant epidemiological data
    - ▶ Place in treatment
    - ▶ Guidelines
  - ▶ Product specific data (e.g. company, compound, INN, ATC, etc.)

# What does the database not do

- ▶ The HSS does not prioritise for countries
- ▶ The HSS does not make any decisions on pricing and reimbursement or market entry
- ▶ Data collected is not tailored to specific countries
- ▶ Data collected is factual with the exception of the high impact reports