MS DATA
ALLIANCE
acting under the umbrella of the
European Charcot Foundation

The MS Data Alliance is a global non-for-profit multi-stakeholder collaboration acting under the umbrella of the European Charcot Foundation, financially supported by a combination of industry partners including Novartis, Merck, Biogen, Janssen, Bristol-Myers Squibb and Roche

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# BECAUSE DATA CAN TRANSFORM THE CARE OF PEOPLE WITH MULTIPLE SCLEROSIS

# Agenda

| Time | Item |
|---|---|
| 10:00 - 10:05 | **Welcome and introduction** |
| 10:05 - 10:15 | **Icebreaker** |
| 10:15 - 11:15 | **Reflection of the state of play with introduction on roadmap concept - Discussion on barriers and status in roadmap** |
| 11:15 - 11:30 | **Concept note and power of decision making** |
| 11:30 - 11:45 | Virtual coffee break |
| 11:45 - 12:45 | **Building your own concept note and roadmap** |
| 12:45 - 13:00 | **Next steps: How to proceed from here?** |

MS DATA ALLIANCE
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ms international federation

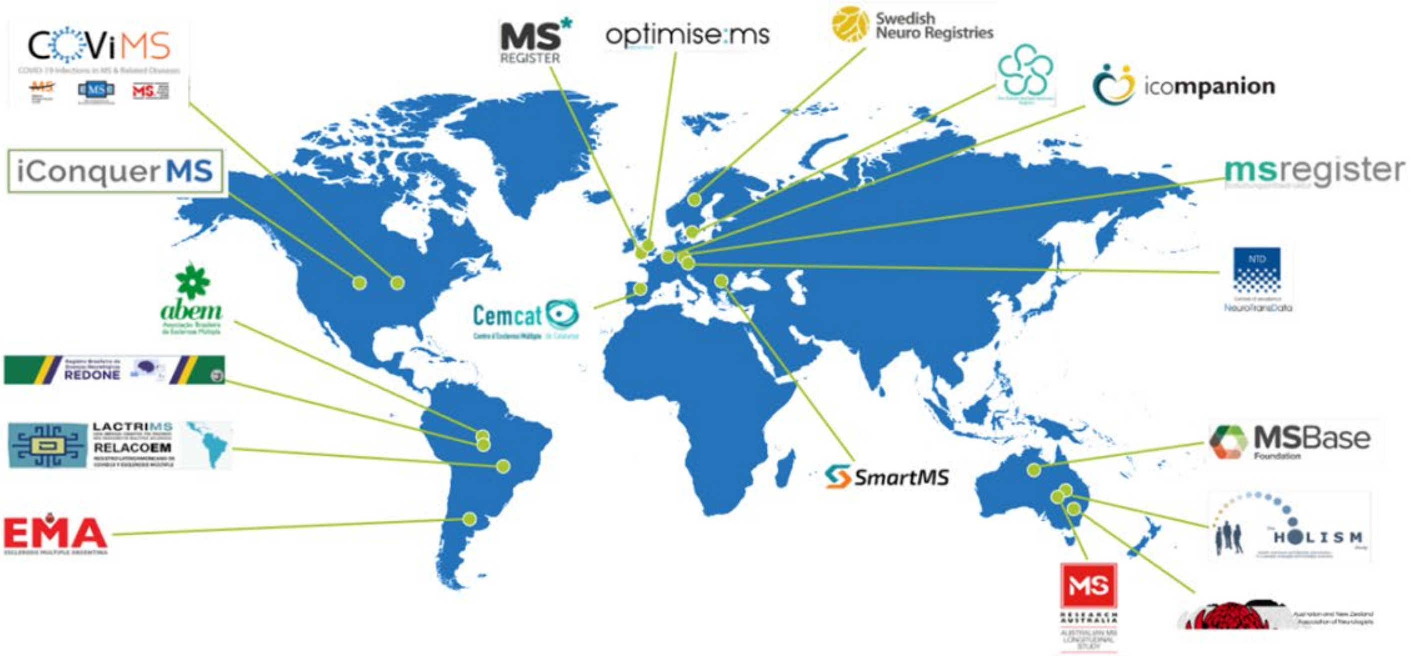
# COVID-19 & MS Global Data Sharing Initiative

**50%**
Increase on number of patient records

**50%**
Increase on number of registries

**< 70%**
Time reduced for weekly data handling

## Resulted in data-driven updated global advise for people with MS on COVID-19 before the summer of 2020



# Key Challenges we aim to overcome

| Sociological Challenges | Technical Challenges |
|---|---|
| The level of **awareness** on the relevance of using real-world MS data at scale differs between individuals. | **Finding** and **assessing** real-world MS data sources that have the potential to address urgent needs within the ecosystem is challenging and time-consuming. |
| **Different stakeholders** have **different needs, issues and concerns** when it comes to real-world data handling and analyses. | Real-world MS data sources are **heterogeneous** in size, maturity and depth. This heterogeneity greatly reduces the potential of collaborative research projects involving several real-world MS data sources. |
| The level of being **informed** about **how** to contribute to the needs of ecosystem as well as the **experience** in actively participating in large-scale real-world collaborative initiatives differs between individuals. | **Executing** large-scale collaborative efforts involving several real-world MS data sources is **challenging** and **time consuming** because of the combined complexity of governance, ethical and legal barriers as well as technical challenges in big data handling and analyses. |

Peeters 2018 Fair Data For Next Generation Management of Multiple Sclerosis. Multiple Sclerosis Journal

# What we do - How to overcome challenges?

| Academy | Toolbox |
|---|---|
| **Raise awareness** about the importance of research using real-world MS data | Tools to reduce the time needed to **find** and **assess** the real-world data sources |
| Build a stakeholder MS data **community** | Tools to reduce the level of **heterogeneity** between different real-world MS data sources |
| **Promote** trustworthy and transparent practices in the use of real-world MS data | Tools to reduce the time needed to **execute** large-scale collaborative efforts involving several real-world MS data sources |

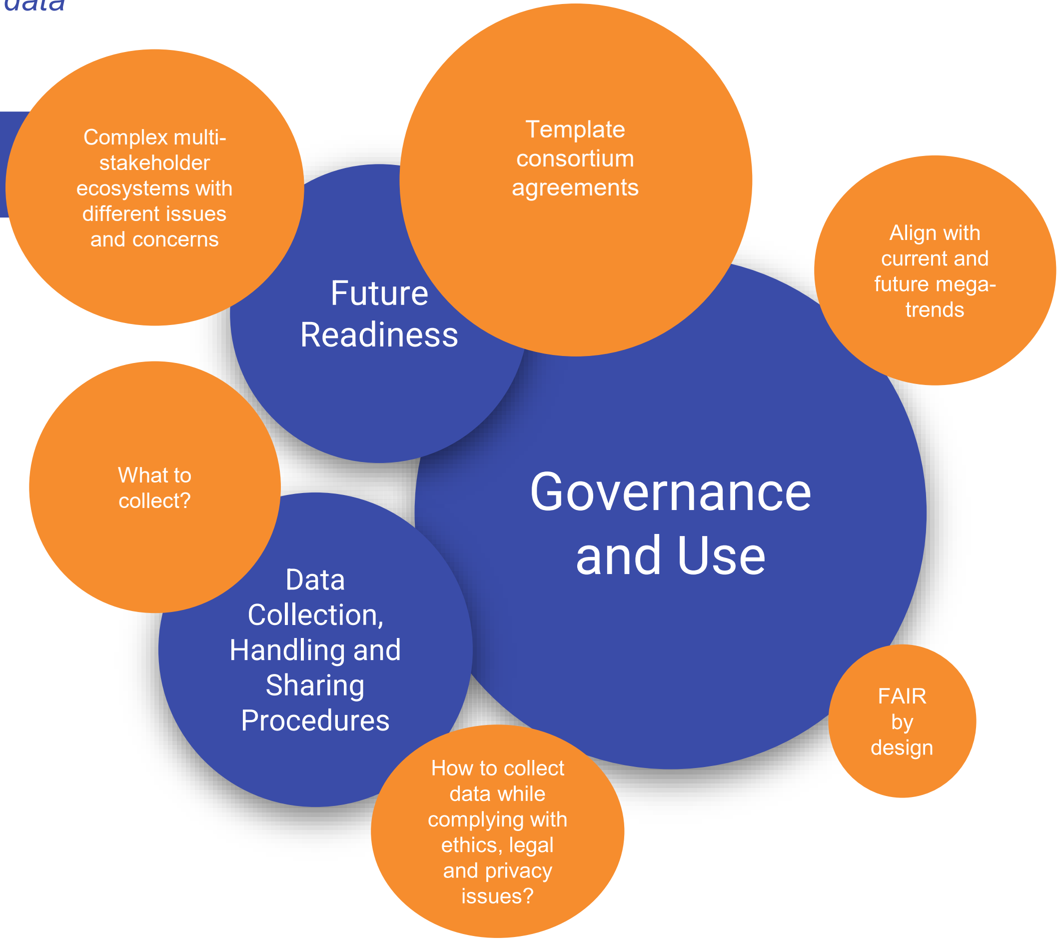
Peeters et al. 2021 Multiple Sclerosis Data Alliance - a global multi-stakeholder collaboration to scale-up real data research. MS and Related Disorders

# First-stop-shop for data science

*With a specific focus on real-world MS data*

## Academy

**Contact us:** msdataalliance.com



Complex multi-stakeholder ecosystems with different issues and concerns

Future Readiness

Template consortium agreements

Align with current and future mega-trends

What to collect?

Governance and Use

Data Collection, Handling and Sharing Procedures

FAIR by design

How to collect data while complying with ethics, legal and privacy issues?

# Facilitate and speed-up large-scale collaborative efforts

*With a specific focus on real-world MS data*

All our tools are (or will be) available in an open source environment and can be easily adapted based on your demands

**Contact us:** msdataalliance.com

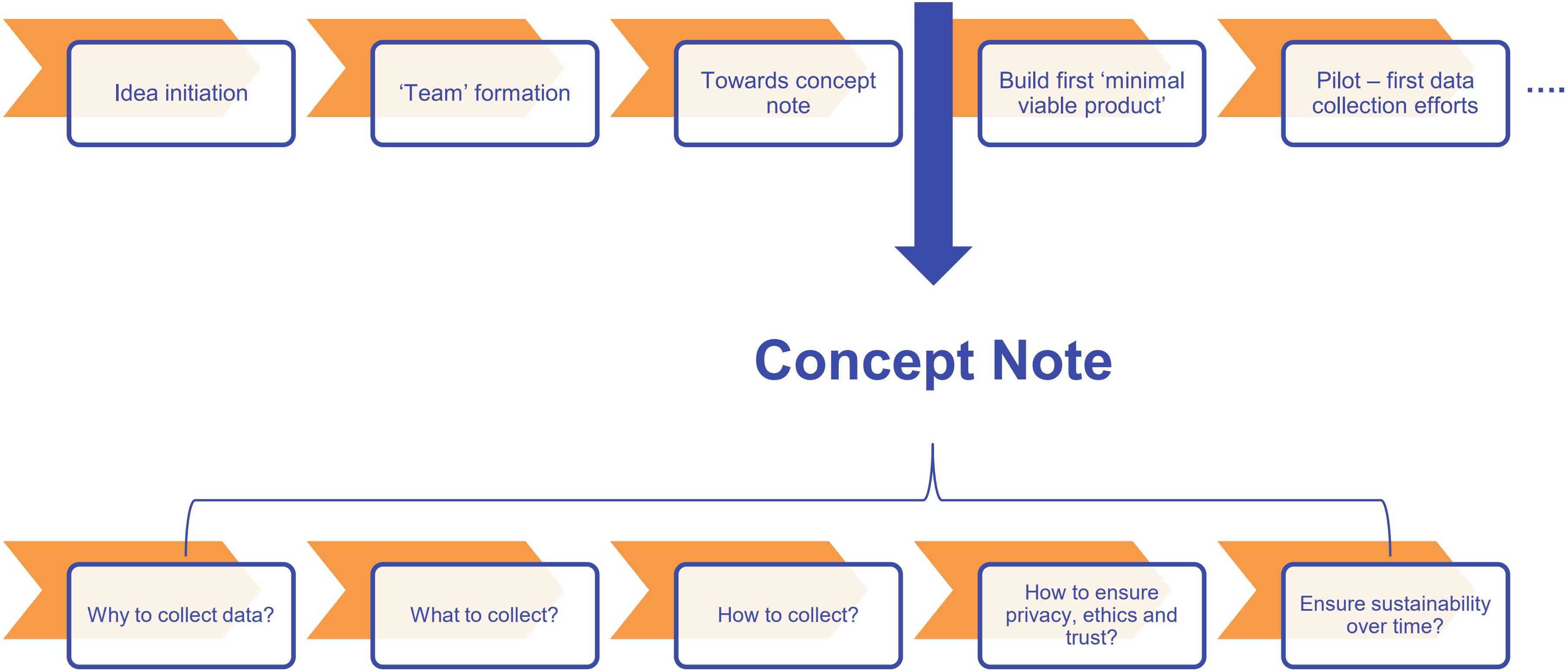
## Toolbox

Tools to reduce the time needed to **find** and **assess** the real-world data sources

Tools to reduce the level of **heterogeneity** between different real-world MS data sources

Tools to reduce the time needed to **execute** large-scale collaborative efforts involving several real-world MS data sources

# Real-World MS Data Registry and Cohort Roadmap



- Idea initiation
- ‘Team’ formation
- Towards concept note
- Build first ‘minimal viable product’
- Pilot – first data collection efforts
- ....

## Concept Note

- Why to collect data?
- What to collect?
- How to collect?
- How to ensure privacy, ethics and trust?
- Ensure sustainability over time?

# Educational Program

*How to set-up a registry*

8 Feb 2023

## Why to set-up a registry?

Value of real-world MS data

22 Feb 2023

## What to collect?

Minimal datasets & recommendations for data collection

8 March 2023

## How to collect?

Data acquisition software systems

22 March 2023

## How to ensure privacy and trust?

Storage, data protection and governance

5 March 2023

## What's next?

Inspiring mega-trends in the real-world MS data arena

**Lotte**
**GEYS**

Tina
PARCIAK

**Marcel**
PARCIAK

**Dipak**
KALRA

**Liesbet**
PEETERS

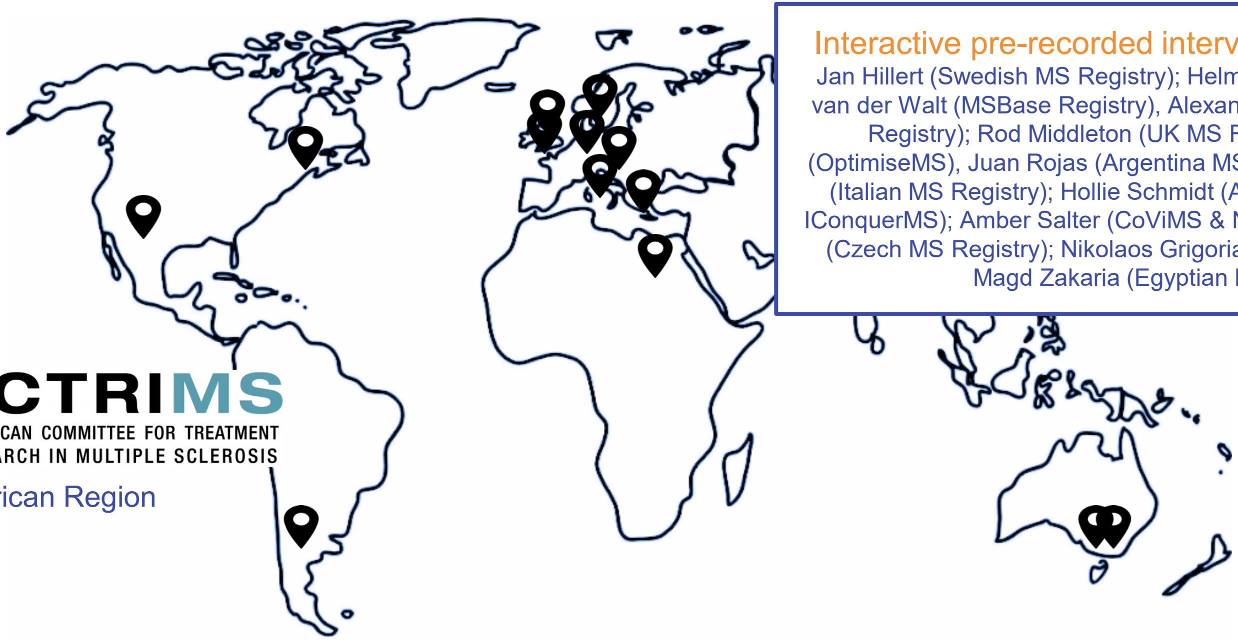
**More information** - msdataalliance.com

# Educational Program

*How to set-up a registry*

Central-Eastern Europe and Balkan Region

emsp EUROPEAN MULTIPLE SCLEROSIS PLATFORM



## Interactive pre-recorded interviews with champions

Jan Hillert (Swedish MS Registry); Helmut Butzkeuven and Anneke van der Walt (MSBase Registry), Alexander Stahmann (German MS Registry); Rod Middleton (UK MS Registry); Ruth Dobson (OptimiseMS), Juan Rojas (Argentina MS Registry); Pietro Iaffaldano (Italian MS Registry); Hollie Schmidt (Accelerated Cure Project & IConquerMS); Amber Salter (CoViMS & NARCOMS); Dana Horáková (Czech MS Registry); Nikolaos Grigoriadis (Greece MS Registry); Magd Zakaria (Egyptian MS Registry)

LACTRIMS
LATIN AMERICAN COMMITTEE FOR TREATMENT AND RESEARCH IN MULTIPLE SCLEROSIS

Latin - American Region

**More information** - msdataalliance.com

# Real-World MS Data Registry and Cohort Roadmap

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**Why** do we want to set-up a Real-World MS Data Registry? – Raise awareness about the need and value

When **we** say **we** – who do we mean? – Identify group of pioneers and stakeholders

Focus on defining **mission, vision and values**

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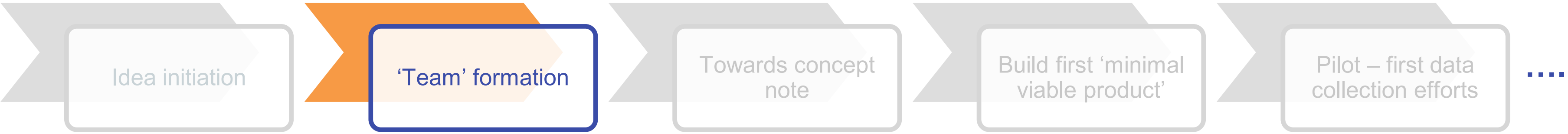
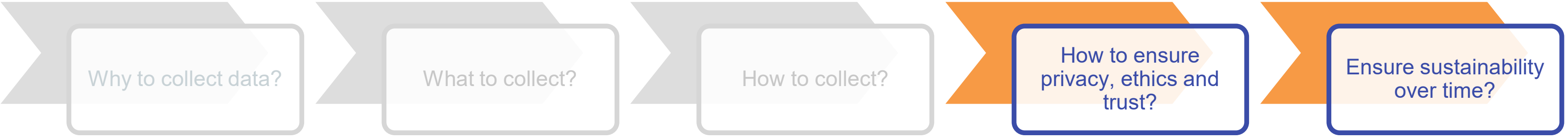


How will we organize ourselves and make **decisions**? – install decision-making bodies

How can we ensure the **trust** of all stakeholders involved? – define governance and use principles

How will the initiative be **funded** (short-term versus long-term)? – define business-and sustainability model



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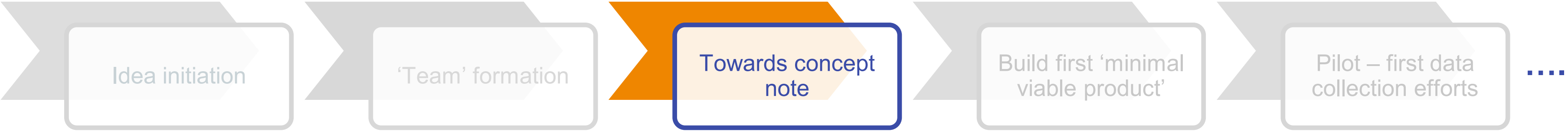
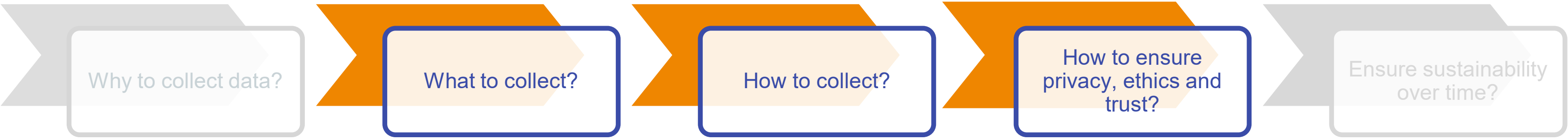
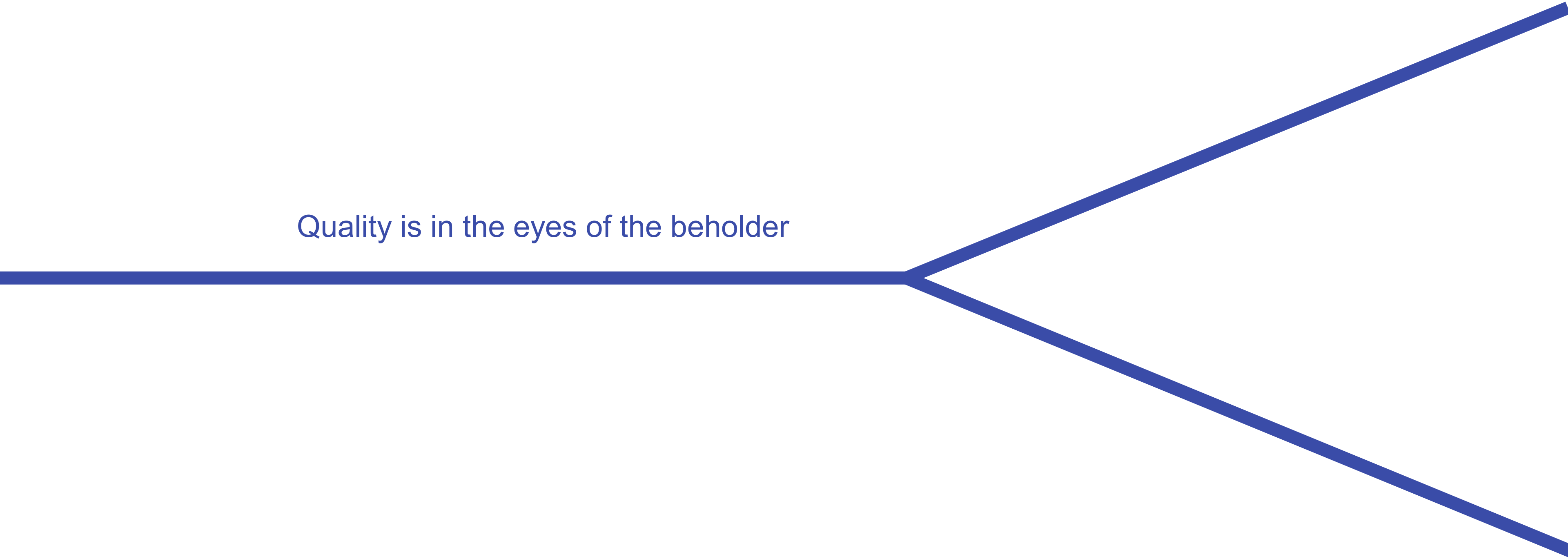


**What** data do we need to achieve our mission? Define detailed list of variables (dictionary)

**How** to collect the data we need? Define detailed data acquisition- and management strategy, including cyber security-, ethics and privacy strategy



# Power of choice



Quality is in the eyes of the beholder

## ***Reasons to*** SHARE?

- Push general knowledge
- Incentivizes researchers to produce and ensure higher quality data for sharing with peers, the scientific community, and the public
- Enables research sponsors to promote and inspire research within a field
- Reduces redundancy of data production in scientific research, which saves investment dollars and time
- Some funder/institution push data sharing

## ***Reasons to use*** SHARED DATA?

- Unique data set access
- Encourages collaboration among researchers to share resources, acquire more data, and produce new findings
- Possibility to perform meta-analyses, which address big picture topics
- Helps to better inform planning and policy

community of
transparancy
& trust

The ones who ***GIVE***

The ones who ***TAKE***

## ***Reasons not to*** SHARE ?

- Inappropriate use of the shared data
- Security concerns over the handling of sensitive or confidential data
- Lack of acknowledgement or citation for the shared data
- Concerns about intellectual property and scooping of ideas

## ***Reasons not to use*** SHARED DATA?

- Concerns about the origin and quality of the data?
- Concerns about intellectual property and scooping of ideas
- Interpretation of research results is complicated and requires interdisciplinary research consortia

Peeters et al. 2019 Multiple Sclerosis Journal

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# Purpose of your Real-World Data Initiative?

**ABBREVIATIONS**

**CEMCAT**
Centre D'esclerosi Multiple De Catalunya

**CIS**
Clinically isolated syndrome

**CLIMB**
Comprehensive Longitudinal Investigation of MS

**EPIC**
MS genetics-, expression, proteomics, imaging clinical

**NARCOMS**
North American Research Committee on MS

**NARCRMS**
North American Registry for Care and Research in Multiple Sclerosis

**OFSEP**
Observatoire Francais de la Sclérose en Plaques

**PROMOPROMS**
new functional PROfile to MOnitor the PROgression of disability in MS

## Regional- or National Longitudinal follow-up

British Columbia MS Database, Danish MS Registry, Italian MS Registry, New York State MS Consortium, OFSEP, Swedish MS Registry

Many other existing and emerging (Canadian Progression Cohort in MS, Corrona MS Registry, Czech MS registry, German MS registries (>3), MS Clinical Database and Registry Health Sciences Centre Winnipeg, SJ MS Center Face to Face Registry, Sonya Slifka Longitudinal MS Study, United Kingdom MS Registry, …)

## Deep phenotyping/ Biobanking

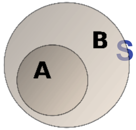
Accelerated Cure Project Registry, CEMCAT CIS Cohort, CLIMB Study, John Hopkins Precision Medicine Center of Excellence for MS, MS EPIC Study, MS Partners Advancing Technology and Health Solutions (MSPaths), MS Sunshine Study, NARCRMS, Norwegian MS Registry & biobank, Swiss MS Cohort, …

## Research Collaborations

Big MS Data Network (BMSD), International MS Genetic Consortium (IMSG), MSBase Neuro-Immunology Registry, MultipleMS, Remote Assessment of Disease and Relapse (RADAR-CNS), Serially Unified Multicenter Multiple Sclerosis Investigation (SUMMIT), …

## Patient-centered

Australian MS Longitudinal Study, iConquerMS™ People-Powered Research Network, NARCOMS, PatientsLikeMe, PROMOPRO-MS, …



## Special target population

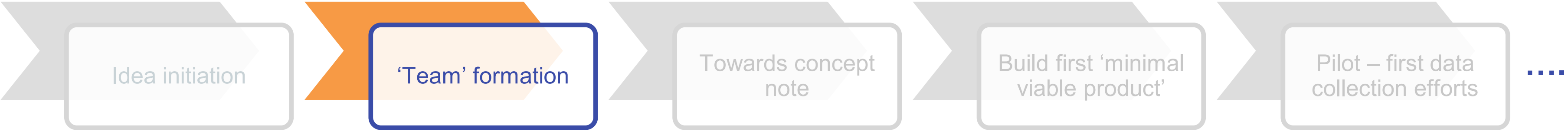
MS in the Hispanic Population (USC Registry), Pediatric MS and Other Demyelinating Diseases (PeMSDD), Sylvia Lawry Centre for MS Research, Veterans Health Administration MS Surveillance Registry (MSSR), …

## Improve care path concept

Cleveland Clinic Knowledge program, MS Documentation System, OptimiseMS, …

Bebo et al. 2017. Multiple Sclerosis Journal
MS Data Alliance Catalogue (msdataalliance.org/tools/Catalogue)
Personal communication custodians

# Real-World MS Data Registry and Cohort Roadmap



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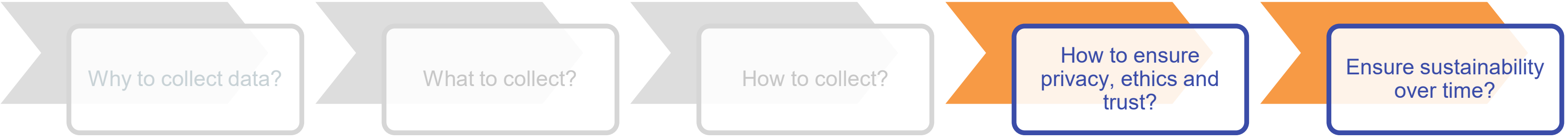
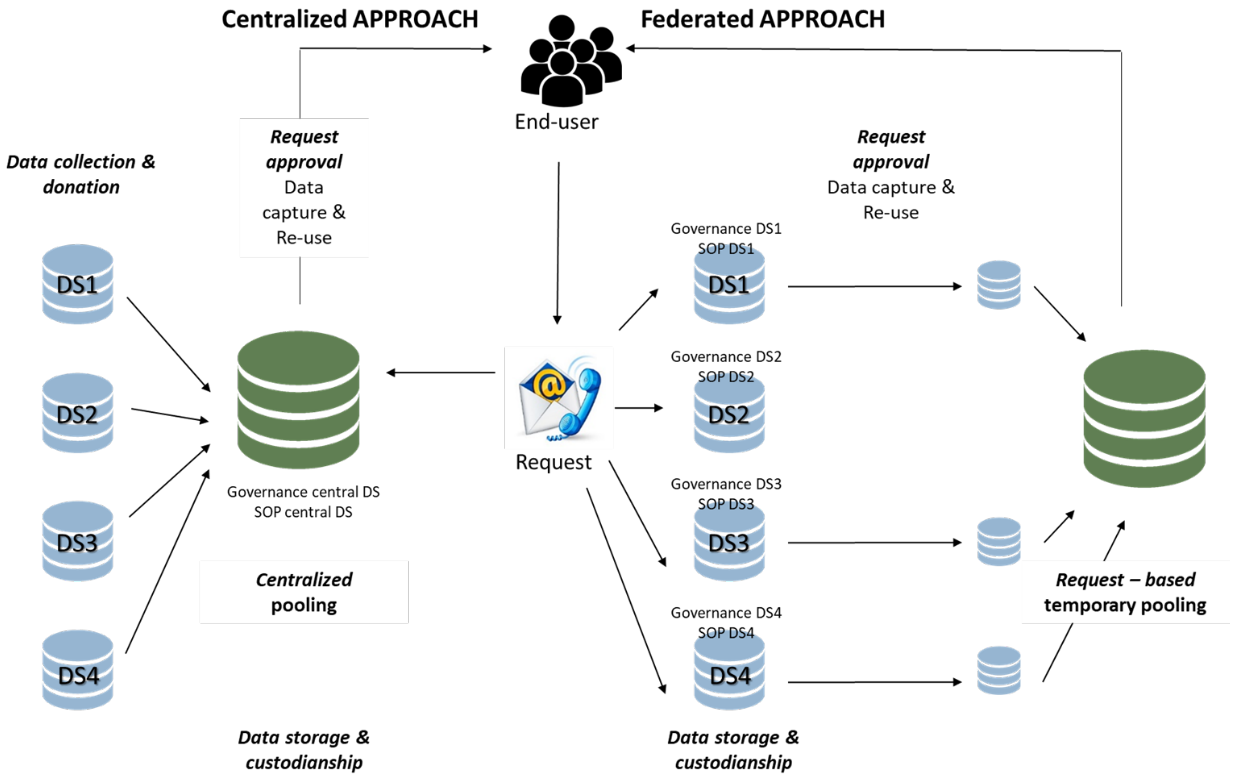


# Governance model of your Real-World Data Initiative?



**Centralized APPROACH**

**Federated APPROACH**

End-user

***Data collection & donation***

***Request approval*** Data capture & Re-use

***Request approval*** Data capture & Re-use

Governance central DS
SOP central DS

***Centralized* pooling**

***Request – based* temporary pooling**

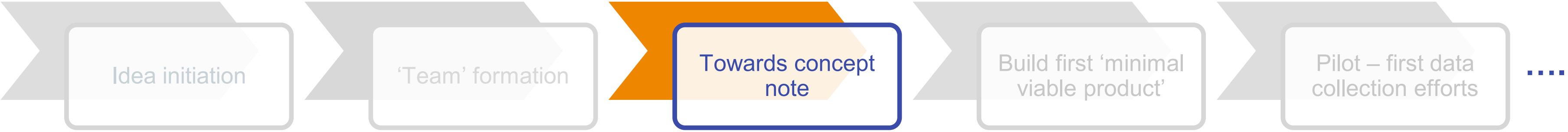
***Data storage & custodianship***

***Data storage & custodianship***

# Governance model of your Real-World Data Initiative?

| Centralized approach | Federated approach |
|---|---|
| Fast request approval, data capture and re-use of data by end-user is possible because the data is already pooled | Fast request approval, data capture and re-use requires clearly define **standard operating procedures because** pooling is performed request-based |
| Data controllers **donate** data to the centralized data source. Custodianship is defined by the governance of the central data source | Data controllers store the data locally and **remain custodian** of the data |
| Although still challenging, ethical and legal requirements of the central data source can be defined more easily | Request-based pooling results in **ethical and legal challenges** at the level of the participating data sources. Guidelines to fulfil these requirements have to be formulated and implemented in the individual data sources |

# Real-World MS Data Registry and Cohort Roadmap



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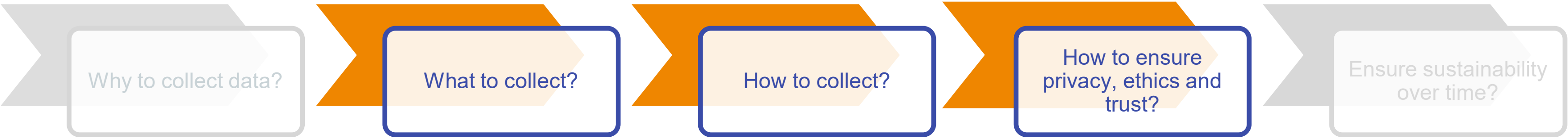

Why to collect data?

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Ensure sustainability over time?

# Patient-reported versus clinician-reported (or both?)

| Physician reported | Patient reported |
|---|---|
| Expert interpretation for clinical outcome measures | Some effects are known only to the patient |
| *Compliance?* Requires physician engagement | *Compliance?* Requires patient engagement |
| Only recording during *visits:* exclusion of patients not regularly visiting/consulting a physician | *Space-and time independent* recording is possible: everyone can participate |
| *Subjectivity and individual interpretation?* Tendency to strive towards international standardisation (e.g. diagnostic criteria, EDSS certification, iPRO initiative, EMA patient registry initiative…) | *Subjectivity and individual interpretation?* (e.g. cultural differences, patient report every symptom important to them irrespectively of the causal relationship, Influence by concomitant feeling, …) |

# Fellowship

**16th November 2022**
**Public Announcement**
Public Announcement of Fellowship Program in Stakeholder Engagement meeting in Baveno & Launch Open Call

**February 2023**
**Kick-off meeting**
1 hour meeting to inform all members of the Committee about the procedures of the Fellowship Program and the evaluation and ranking system

**1st March 2023**
**Deadline applications**
Deadline for Fellowship applications at 17h00 CEST

Approx. 3 weeks to review applications (max 5 per Committee Member)

**Week of 20 March 2023**
**Deadline written evaluation & Consensus building and final decision meeting**
All Committee Members provide a written summary of their review of the application (templates will be provided)

**4-5 May 2023**
**Award Ceremony**
Award Ceremony at EMSP Annual Conference in Helsinki, Finland

Apply here: https://www.msdataalliance.org/academy/fellowshipProgram

# This activity was supported by:

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