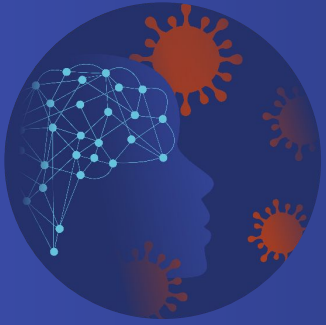




COVID-19 & MS  
Global Data Sharing Initiative

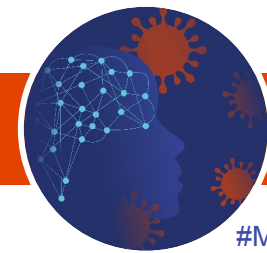




# Mapping exercise of COVID-19 vaccines protocols

version March 2021





In March 2020, a COVID-19 in MS core dataset was defined (more information [here](#)). Aligning data collection protocols as early as possible has proven to facilitate collaborative research.

To support alignment in updating COVID-19 in MS surveys and data collections and to facilitate collaborative research between initiatives, we have performed a mapping exercise of COVID-19 vaccines protocols. The mapping exercise is a read up on current initiatives (not-MS specific) and already existing data dictionaries for MS registers/cohorts containing questions towards COVID-19 vaccination to get an overview of collected variables.

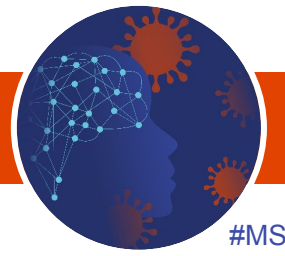
The aim of this document is to summarize the first intermediate results of the mapping exercise (on the 16<sup>th</sup> of March 2021).

The document is structured as follows:

- PART I: summary on **not-MS** specific protocols
- PART II: summary on **MS** specific protocols

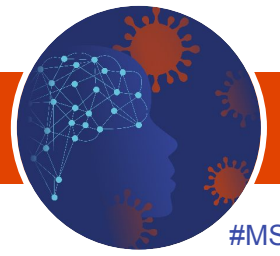
We aim to provide regular updates when appropriate. We welcome additional information / comments and suggestions.

Reach out to us! Contact: [tina.parciak@uhasselt.be](mailto:tina.parciak@uhasselt.be)



- 1. Literature and web review on general COVID-19 vaccines data dictionaries/surveys/protocols**
  - a. Checked EMA / WHO / CDC / OHDSI / Vaccinnet / ...
  - b. General web search for data collection on COVID-19 vaccination (pharmacovigilance / safety studies / national vaccination protocols / ...)
  
- 2. Comparing data dictionaries/surveys/protocols of already existing (or emerging) COVID-19 in MS initiatives where data on COVID-19 vaccines is collected**
  - b. Reached out to data partners of [GDSI](#)
  - c. Reached out to partners in [MSDA Catalogue](#) that collect data on COVID-19
  - d. Reached out to other people in our network

# First findings (8<sup>th</sup> of March 2021)



#MSCOVID19

- Regarding COVID-19 vaccination, there are hardly any public / international protocols available yet.
- Although the importance of alignment and cooperation is stressed by most regulatory decision makers (e.g. EMA, FDA or WHO), no actual data protocol can be found.
- General information on COVID-19 vaccine (safety) protocols:  
the identification of smaller / mostly national efforts and the discovery of the corresponding data protocols was a tricky task.
- MS specific information on COVID-19 vaccine data:  
As of today (16<sup>th</sup> of March), we received 6 dictionaries / surveys from MS-specific registries / cohorts (3 PRO / 3 clinician reported/PRO) containing data on COVID-19 vaccines, and additionally some general COVID-19 in MS dictionaries/surveys.

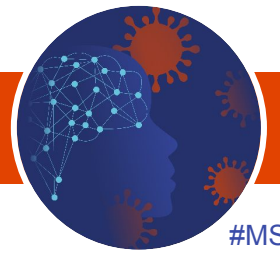


# PART I: summary on not-MS specific protocols

(a more detailed description of the protocols can be found [here](#))



# Not-MS specific data protocols / collected variables



#MSCOVID19

## Based on information of:

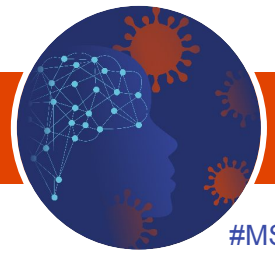
- Centers for Disease Control and Prevention (CDC)
- Vaccinnet (Belgium)
- European Medicines Agency (EMA) website
- Clinical trial protocol Moderna COVID-19 mRNA Vaccine (ATC code J07BX03)
- EudraVigilance (EMA)
- Safety Platform for Emergency vACcines (SPEAC)
- World Health Organisation (WHO)

## Identified categories\*:

- Personal data of vaccinated person
- Comorbidities
- (COVID-19 history)
- COVID-19 vaccine (general information)
- COVID-19 vaccine administration
- Vaccinator
- Adverse reactions/events after vaccination
- Serology/Immunogenicity assessments

\*The variables in the identified categories show overlap with the [current core dictionary of the COVID-19 in MS GDSI](#). The aim of the general online search on COVID-19 vaccine variables is to identify in general what variables are of interest for COVID-19 vaccination studies.

# Not-MS specific data protocols / collected variables



#MSCOVID19

## Category: Personal data vaccinated person

Variable
National Insurance number/ID
Gender*
Date of Birth
Age*
Place of Birth (Country**)
Date of Death
Race
Ethnicity
Geographic Origin

## Category: Comorbidities

Variable
Comorbidity*

## Category: COVID-19 history\*

Variable
Confirmed earlier episode of COVID-19*
Person no longer suffers of COVID-19*

\* covered in [GDSI COVID-19 in MS core dataset \(more information\)](#)

\*\*e.g. ISO Codes for countries: <https://www.iso.org/obp/ui/#search>



# Not-MS specific data protocols / collected variables



#MSCOVID19

## Category: COVID-19 vaccine (general information)

Variable
Identification code*
Lot number
Registration date of the vaccine (date of recording in the registry)
Vaccine type
Manufacturer
Expiration date

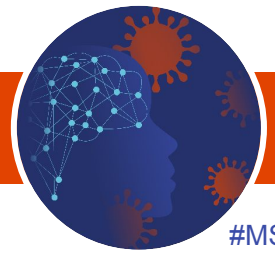
## Category: COVID-19 vaccine administration

Variable
Is the person vaccinated?
Administration date
Administered dose
Vaccination place (code identifying the vaccination location)
Administration site
Administration route
Dose number
Vaccination series complete
Refused vaccination, and reason why

\* Representation through ATC: The Anatomical Therapeutic Chemical Classification.

ATC is an internationally accepted classification system for medicines that is maintained by the World Health Organisation (WHO)

# Not-MS specific data protocols / collected variables



#MSCOVID19

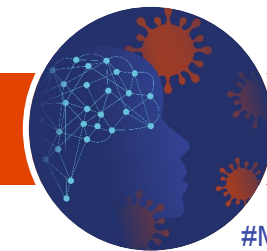
## Category: Vaccinator

Variable
Vaccinator  (physical clinic or facility that reported the vaccination)
Vaccinator type  (who registered the vaccination: Doctor, Doctors Practice, Organization)
Vaccinator identification  (accreditation number of doctor who registers the vaccine)

## Category: Adverse reactions/events after COVID-19 vaccination

Variable
Incidence of adverse events
Adverse Event (AE)
Concomitant medication
AE reporting date
Reporter group (Who reported the AE? Healthcare professional/Non Healthcare professional/ Not specified)
Seriousness
Serious AE (SAE)

# Not-MS specific data protocols / collected variables



#MSCOVID19

## Category: Adverse reactions/events after COVID-19 vaccination\*

## Category: Serology/Immunogenicity assessments

Variable
AE reaction group and Adverse reaction** ( <u>EudraVigilance</u> )
Adverse reactions
Grade of adverse reaction
AE of special interest (AESI)***

Variable
Positive serology (antibody test) result?
Serum bAb levels against SARS-CoV-2 as measured by ligand-binding assay specific to the SARS-CoV-2 S protein****
Serum bAb levels against SARS-CoV-2 as measured by ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein****
Serum nAb titer against SARS-CoV-2 as measured by pseudovirus and/or live virus neutralization assays****

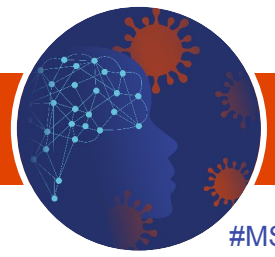
\* FYI: FDA Briefing document Moderna COVID-19 vaccine (5.2.6 Safety: p31-46)

\*\* Suspected AE's per reaction group can be found on this [link](#)

\*\*\* [SPEAC AESI list](#)

\*\*\*\* no specific information available / part of [Moderna clinical trial](#) (you need to register and log in on EMA to get access)

# Standardized coding for COVID-19 vaccines and related terms

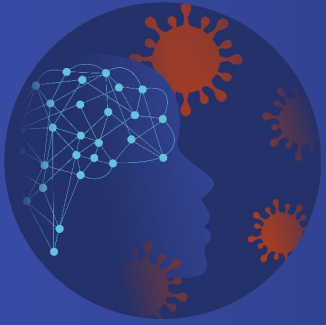


#MSCOVID19

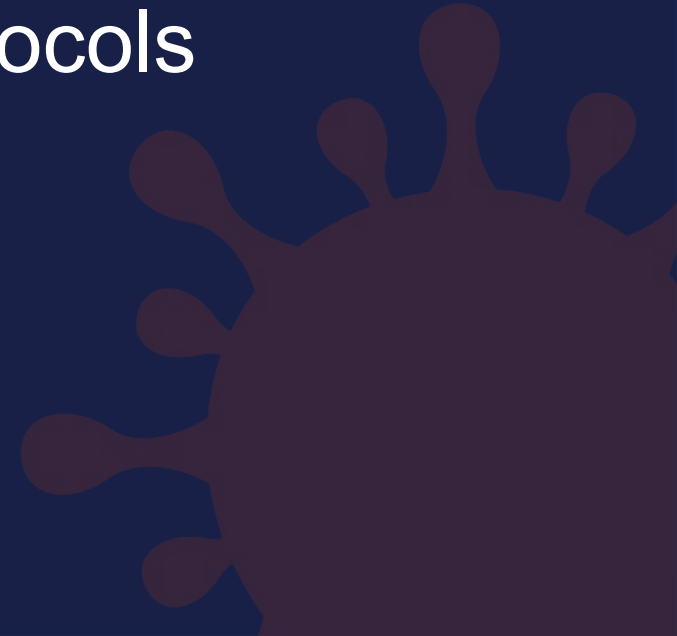
- Immunization Information Systems ([IIS](#)) (used by CDC)
- [MedDRA](#) (used in Moderna clinical trial to code AE's and medical history)
- [WHODrug](#) (used in Moderna clinical trial to code medications)
- [SNOMED CT COVID-19 related content](#)
- [WHO ICD-10 codes for special purposes](#)

## Exemplary representation using standard code: OMOP Common Data Model

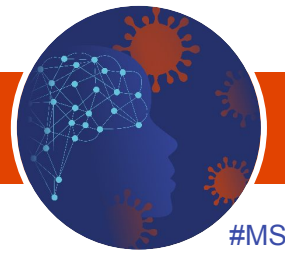
Brand name	Coding name	OMOP concept_id
Moderna COVID-19 vaccine	SARS-CoV-2 (COVID-19) vaccine / mRNA-1273 0.2 MG/ML Injectable Suspension	37003518
Pfizer-Biontech COVID-19 Vaccine	SARS-CoV- (COVID-19) vaccine / mRNA-BNT162b2 0.1 MG/ML Injectable Suspension	37003436
AstraZeneca COVID-19 Vaccine	SARS-COV-2 (COVID-19) vaccine / vector non-replicating / recombinant spike protein-ChAdOx1 / preservative free / 0.5 mL	724905
Janssen COVID-19 Vaccine	SARS-COV-2 (COVID-19) vaccine / vector non-replicating / recombinant spike protein-Ad26 / preservative free / 0.5 mL	702866



## **PART II: summary on MS specific protocols**



# MS specific data protocols / collected variables

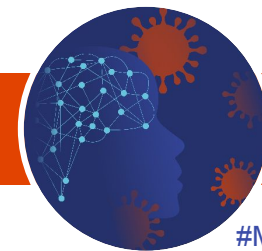


#MSCOVID19

## Identified categories:

- General vaccination history
- COVID-19 vaccine willingness and info
- COVID-19 vaccine administration
- COVID-19 vaccine name/type/brand
- COVID-19 vaccination adverse reactions
- COVID-19 vaccination and the effect on MS
- (COVID-19 infection after vaccination)

# MS specific data protocols / collected variables



#MSCOVID19

## Category: General vaccination history (PRO oriented)

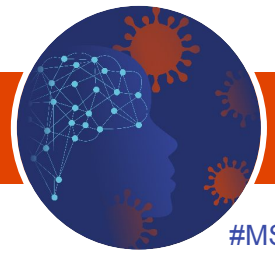
Variable	Representation
Do you think vaccinations in general are important?	Yes / No / Unknown
Childhood vaccinations?	Yes / No / Unknown
Why not?	*
Adolescence vaccinations?	Yes / No / Unknown
Why not?	*
Flu vaccination? (ever/ annually/ never/ sometimes)	Yes / No / Unknown
Reactions to vaccinations before?	Yes / No / Unknown

\* Several options of representation.

Examples: "Because of what my parents/I have read/seen/heard in the press" or " Because my parents/I have been advised not to by someone close to me" or "My parents were/I am not comfortable with going to a healthcare environment at that/the moment"

See the data dictionary/survey of [the UK MS register](#), [COVER-MS project](#) and [HELANI](#) for more information.

# MS specific data protocols / collected variables



#MSCOVID19

## Category: COVID-19 vaccine willingness and info (PRO oriented)

Variable	Representation
Will you get vaccinated (once it's available)?	Yes / No / Unknown
Why (not)?	*
Information / advice on COVID-19 vaccines	**
Barriers to get COVID-19 vaccination?	**

\* see slide before

\*\* Several options of representation.

For information source about COVID-19 vaccination: e.g. "The News", "Social Media" or "Family"

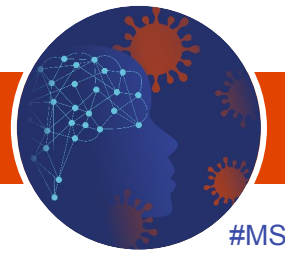
For information status: e.g. "How well-informed are you regarding COVID vaccination?"

For barriers to get COVID-19 vaccination: e.g. "I'm not yet eligible to receive the vaccine" or "I don't know how or where to get the vaccine"

See the data dictionary/survey of [the UK MS register](#), [COVER-MS project](#) and [HELANI](#) for more information.



# MS specific data protocols / collected variables

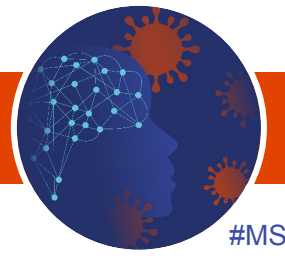


#MSCOVID19

## Category: COVID-19 vaccine administration

Variable	Representation
Vaccinated against COVID-19?	Yes / No
Date of vaccine administration (first)	date (yyyy-MM-dd)
Date of vaccine administration (second)	date (yyyy-MM-dd)
Location of administration	Hospital / GP / Vaccination centre / Residential or nursing home / Other
Antibody test after vaccination?	Yes / No / Yes, AB+ / Yes, AB- / Unknown

# MS specific data protocols / collected variables

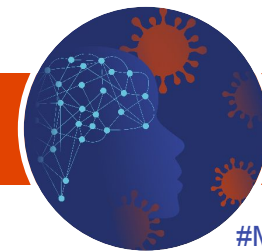


#MSCOVID19

**Category: COVID-19 vaccine name/type/brand (Generic name: "SARS-CoV-2 (COVID-19) vaccine")**

Variable	Representation
COVID-19 Vaccine Moderna	mRNA-1273
Comirnaty/COVID-19 Vaccine Pfizer-BionTech	mRNA-BNT162b2
COVID-19 Vaccine AstraZeneca	AZD1222
COVID-19 Vaccine Janssen (Johnson & Johnson)	Ad26.COVS.2
CureVac	CVnCoV
Gamaleya	Sputnik V
Vector Institute	EpiVacCorona
Novavax	NVX-CoV2373

# MS specific data protocols / collected variables

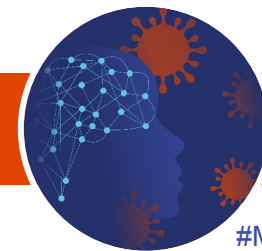


#MSCOVID19

**Category: COVID-19 vaccine name/type/brand (Generic name: "SARS-CoV-2 (COVID-19) vaccine") (continued)**

Variable	Representation
Sinopharm	BBIBP-CorV
Sinovac	CoronaVac
Bharat Biotech	Covaxin/ BBV152 A/ B/ C
CanSino	Ad5-nCoV
Serum Institute of India	Covishield
Other	
Unknown	

# MS specific data protocols / collected variables

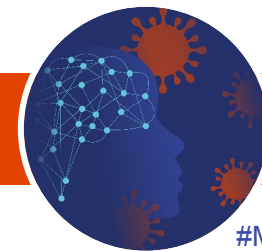


#MSCOVID19

## Category: COVID-19 vaccination adverse reactions

Variable	Representation
Adverse reactions?	Yes / No / Unknown (=not sure)
Date of adverse reaction	date (yyyy-MM-dd)
Type of adverse reactions	CR: "local reactions (at injection site)" PRO: "reactions at injection site (redness / swelling / pain / warmth / itch)" <i>(= suggestion for grouping several injection site related adverse reactions found during the mapping)</i>
	Loss of feeling / function (injection site area)
	Chills
	Fatigue
	Fever
	Headache
	Joint pain

# MS specific data protocols / collected variables

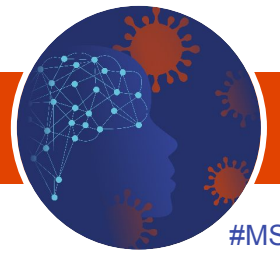


#MSCOVID19

## Category: COVID-19 vaccination adverse reactions (continued)

Variable	Representation
	Muscle ache (other than injection site)
	Gastrointestinal reactions
	Allergic reaction
	Rash
	Dizziness
	Malaise (general feeling of discomfort / illness or uneasiness)
	Paresthesia
	Tachycardia
	Lymphadenopathy
	Flu-like sickness
	Other
Severity of adverse reaction	Mild (very minor) / Moderate / Severe (required treatment)
Moment of adverse reaction	Immediately / Within an hour / Within 24 hours / Within 48 hours / Within 7 days / Within two weeks / More than two weeks
Adverse reaction persisting?	Yes, still / No, subsided (after x days)

# MS specific data protocols / collected variables



#MSCOVID19

## Category: COVID-19 vaccination and the effect on MS

Variable	Representation
Any new or changed MS symptoms after vaccination?	Yes / No
If yes, which symptoms?	Fatigue / Spasticity or Stiffness / Bodily pain / Paraesthesia / Bladder or Bowel issues / Gait or walking issues / Hand function or Dexterity / Dizziness / Visual impairment / Cognitive impairment / Depression / Other