COVID-19 & MS
Global Data Sharing Initiative
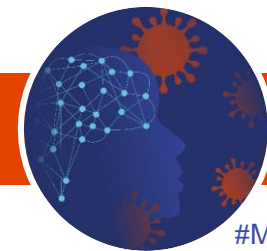
Mapping exercise of COVID-19 vaccines protocols

v2.0 May 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.
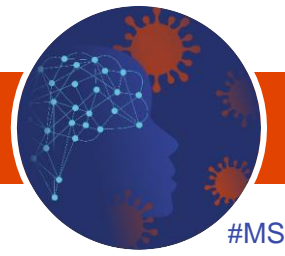
The aim of this document is to summarize the intermediate results of the mapping exercise. We aim to provide regular updates when appropriate and we welcome additional information/comments and suggestions. Reach out to us: tina.parciak@uhasselt.be
Version history:

- v1.0: 16th of March 2021
- v2.0: 06th of May 2021

The document is structured as follows:

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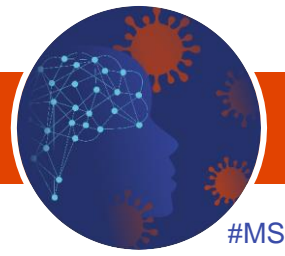- PART II: summary on **MS** specific protocols

1. **Literature and web review on general COVID-19 vaccines data dictionaries/surveys/protocols**

    a. Checked EMA / FDA / WHO / CDC / OHDSI / Vaccinnet / VAERS / BEST / CMS / ...

    b. General web search for data collection on COVID-19 vaccination (pharmacovigilance / safety studies / national vaccination protocols / ...)

1. **Comparing data dictionaries/surveys/protocols of already existing (or emerging) COVID-19 in MS initiatives where data on COVID-19 vaccines is collected**

    a. Reached out to data partners of GDSI

    b. Reached out to partners in MSDA Catalogue that collect data on COVID-19

    c. Reached out to other people in our network

EMA: European Medicine Agency; FDA: Food and Drug Administration; WHO: World Health Organisation; CDC: Centers for Disease Control and Prevention; OHDSI: Observational Health Data Sciences and Informatics; Vaccinnet; VAERS: Vaccine Adverse Event Reporting System; BEST: Biologics Effectiveness and Safety Initiative; CMS: Centers for Medicare & Medicaid Services

- 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 (6th of May), we received 8 dictionaries/surveys from MS-specific registries/cohorts (2 clinician reported / 2 PRO / 4 clinician reported/PRO) containing data on COVID-19 vaccines, and additionally some general COVID-19 in MS dictionaries/surveys.
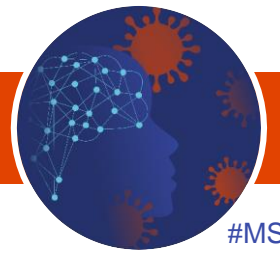
EMA: European Medicine Agency; FDA: Food and Drug Administration; WHO: World Health Organisation; PRO: Patient-Reported Outcome

PART I: summary on not-MS specific protocols

A more detailed overview of the protocols/information found online can be found here *(updated in May 2021)*

Not-MS specific data protocols / collected variables
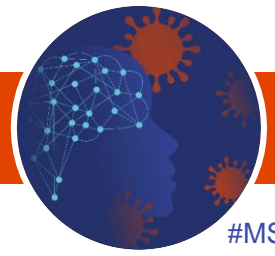
Based on information of:
- World Health Organisation (WHO)
- Centers for Disease Control and Prevention (CDC)
- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- EudraVigilance (EMA)
- Clinical trial protocol Moderna COVID-19 mRNA Vaccine (ATC code J07BX03)
- Safety Platform for Emergency vACcines (SPEAC)
- Vaccinnet (Belgium)

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
- COVID-19 vaccine willingness and info

*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

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
Occupation / Health worker role
BMI (height, weight) / Obese Smoking history

Category: Comorbidities

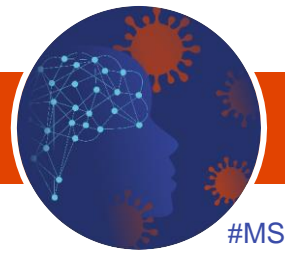| Variable |
| --- |
| Comorbidity* / Presence of chronic disease(s) |

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

Category: COVID-19 vaccine (general information)

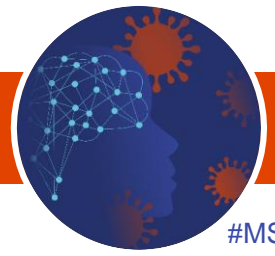| Variable |
| --- |
| Identification code* |
| Lot number |
| Registration date of the vaccine (date of recording in the registry) |
| Vaccine type |
| Manufacturer |
| Expiration date |

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

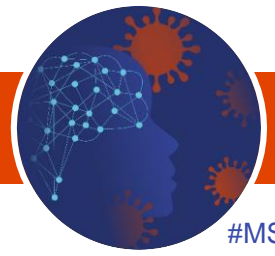## Category: Vaccinator

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)

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

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

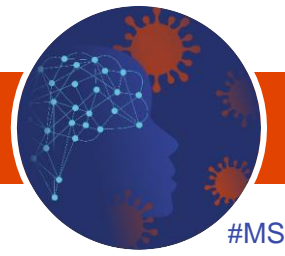## Category: Serology/Immunogenicity assessments

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)*

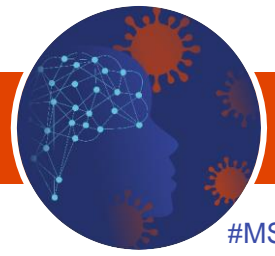## COVID-19 vaccine willingness and info*

Variable
Have you ever received a vaccine as an adult?
Have you received a COVID-19 vaccine? / If a COVID-19 vaccine is available to you, will you get it? / How much do you want to get a COVID-19 vaccine?
Do you know where to go get a COVID-19 vaccine for yourself? / How easy is it to get a COVID-19 vaccine for yourself?
How concerned are you about getting COVID-19?
How do you feel about the COVID-19 vaccine(s)?
How much do you trust the new COVID-19 vaccines?
How important do you think getting a COVID-19 vaccine will be for your health?
How much do you think getting a COVID-19 vaccine for yourself will protect other people in your community from COVID-19?
How safe do you think a COVID-19 vaccine will be for you?
How concerned are you that a COVID-19 vaccine could cause you to have a serious reaction?
Have you seen or heard anything bad about COVID-19 vaccines?

*adapted from WHO-Data for action: achieving high uptake of COVID-19 vaccines

- Immunization Information Systems (IIS) (used by CDC)

- MedDRA (Medical dictionary for Regulatory Activities) (developed by ICH, open to use by anyone, 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 + ICD-10-CM Official Guidelines for Coding and Reporting

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

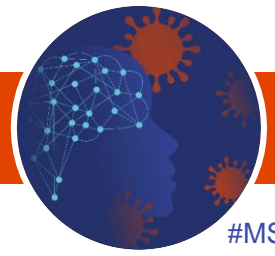*No changes compared to v1.0 (March 2021)*
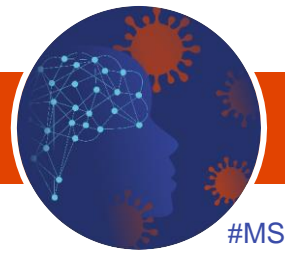
Identified categories:

- 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 – not included since the variables (date of infection, treatment, symptoms…) are covered in the COVID-19 in MS core dataset)*

MS specific data protocols / collected variables

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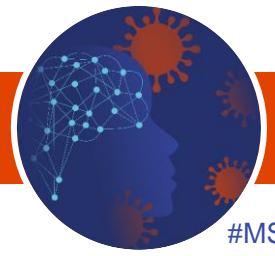
Category: COVID-19 vaccine willingness and info (PRO oriented)

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
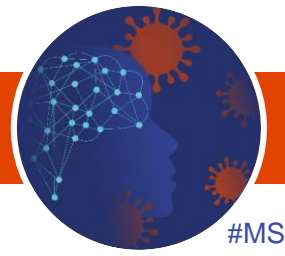
Category: COVID-19 vaccine administration

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

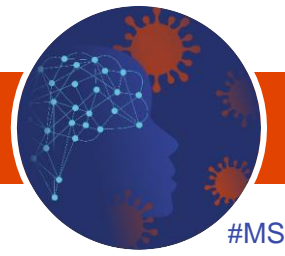# MS specific data protocols / collected variables
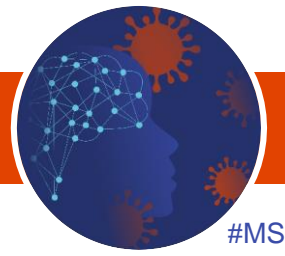
Category: COVID-19 vaccine name/type/brand (Generic name: "SARS-CoV-2 (COVID-19) vaccine")

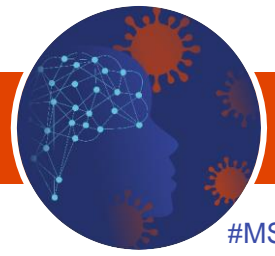| Variable	Representation
COVID-19 Vaccine Moderna	mRNA-1273
Comirnaty/COVID-19 Vaccine Pfizer-BionTech	mRNA-BNT162b2
COVID-19 Vaccine AstraZeneca	AZD1222
COVID-19 Vaccine Janssen (Johnson & Johnson)	Ad26.COV2.S
CureVac	CVnCoV
Gamaleya	Sputnik V
Vector Institute	EpiVacCorona
Novavax	NVX-CoV2373

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

Category: COVID-19 vaccination adverse reactions

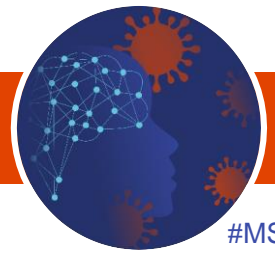| Variable	Representation
Adverse reactions?	Yes / No / Unknown (=not sure)
Date of adverse reaction	date (yyyy-MM-dd)
Type of adverse reactions	CR: "local reactions (at injection site)" PRO: "reactions at injection site (redness / swelling / pain / warmth / itch) *(= suggestion for grouping several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

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

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