DRIVE Open data strategy

Laurence Torcel-Pagnon, Vincent Bauchau, Kaat Bollaerts, Toni Carmona, Cintia Munoz and Javier Diez-Domingo

on behalf of WP1

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DRIVE objectives

A sustainable study network for brand-specific influenza vaccine studies in the EU

A governance model for transparent, scientifically robust public-private partnerships

Long term vision for the post-DRIVE: build on the existing infrastructure to expand for the regulatory evaluation of brand specific vaccines effectiveness against respiratory diseases including Influenza and COVID-19

Positive feedback from EMA
DRIVE acknowledged in ACCESS project under FISABIO lead
(EMA tender - Feasibility analysis of an EU infrastructure for COVID-19 vaccine monitoring)
Why Open Data is a MUST

To promote research collaboration between sites and advanced knowledge in IVE

To attract more sites in DRIVE study platform and enable robust BSIVE with larger pool of data

To value sites data through scientific publications

To support post-DRIVE sustainability and recognition though transparent data model
Current EU position about open data/access

ECDC communication strategy 2020
Guiding principles
Reuse

41. ECDC will also engage further with other platforms such as the EU Open Data Portal to make European public health data available to a wider audience and facilitate reuse.

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Guidelines to the Rules on
Open Access to Scientific Publications
and
Open Access to Research Data
in Horizon 2020

FAIR initiative (aim: make research data Findable, Accessible, Interoperable and Reusable)
Fast move with COVID-19 pandemic

About this portal

The COVID-19 Data Portal was launched in April 2020 to bring together relevant datasets for sharing and analysis in an effort to accelerate coronavirus research. It enables researchers to upload, access and analyse COVID-19 related reference data and specialist datasets as part of the wider European COVID-19 Data Platform.

Should DRIVE upload COVID-19 collected data in 2020-21?

- Centralization of the data transfer
- Acknowledgement of sites contribution
- Collaboration and visibility for DRIVE study platform

- Need to evaluate the workload
- Better understand how data are stored and shared
Data sharing: several initiatives

✓ Finland (Near-real time flu vaccine effectiveness online)
✓ GISAID (Genomic epidemiology, rapid data sharing, influenza and SARS-COV-2 viruses)
✓ TESSY (ECDC), disease surveillance data
✓ Clinical trial data from Pharma companies
✓ ODSHI (OMOP): open collaboration, open codes and standards, mostly contribution in kind
✓ EMIF, EHDEN: database network, ‘market space’
✓ VSD, PRISM: large public funding (FDA, US)
✓ OpenPHACTS
✓ CPRD: database curated and open for research, fees
✓ US claims, such as Marketscan (fraud detection, data quality, benchmarking ...)

DRIVE
What DRIVE is currently sharing?

First step

Vaccine

*Title:* Vaccine effectiveness against laboratory-confirmed influenza in Europe – results from DRIVE network during season 2018/19

If accepted the publication will be open access

**Methods**

“*Aggregated data from the DRIVE studies are available upon request from* info@drive-eu.org.”

**Discussion**

“*Due to the meta-analytic approach chosen, DRIVE is also able to incorporate data from sites that only share aggregated data. To encourage data-sharing, aggregated data for this study are available upon request.*”

Sharing of **core aggregated dataset** through yearly reports publicly available on DRIVE website

*Number of cases/controls exposed and unexposed within strata (age/setting/design/brand)*  
-> web-appendix for season 2019-20  

[https://www.drive-eu.org/](https://www.drive-eu.org/)
What to share?

Sharing **aggregated data created** upon request with more covariates

Sharing **de-identified patient-level data** *(when allowed by site)*

How to share?

FOR SITES/DATA CONTRIBUTORS
Adhering to DRIVE data access agreement *(to be drafted)*

Giving access to `restricted area' at DRIVE ESSA platform *(to be activated)*

With whom to share?

Fully open to: current sites and new sites/data contributors

Upon request if relevant research question to any third party including industry *(to be defined)*
DRIVE: Upon request model
For non DRIVE data contributors

Third Party

Pre filled in a specific form in DRIVE website to request use of DRIVE data for a specific Research (attached study concept/protocol, SAP)

Scientific committee review the Request ⇒ Assess scientific relevance

Review by Central Data Management Entity to assess technical components for feasibility

Go/No GO (consensus based on principles)

Agreement with Fisabio, to set the conditions of the use (Data, Research, intellectual property rights, limit of the use..) with no profit

Propose predefined limited fees to cover contract arrangement and database preparation/maintenance

NO GO

Scientific committee and Central Data Management Entity justification