



# DRIVE

Development of Robust  
and Innovative Vaccine  
Effectiveness

# DRIVE Open data strategy

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on behalf of WP1



#### **Acknowledgement**

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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

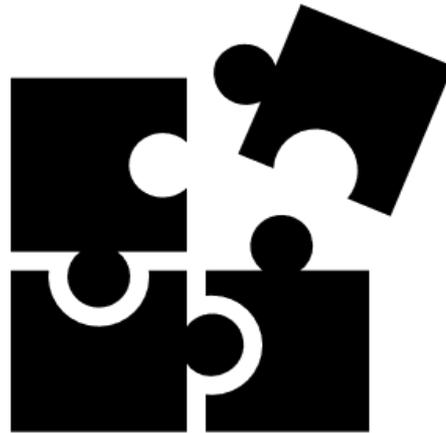


Positive feedback from EMA  
DRIVE acknowledged in ACCESS project under FISABIO lead  
*(EMA tender - Feasibility analysis of an EU infrastructure for COVID-19 vaccine monitoring)*

# 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 through 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 re-use.

## OPEN ACCESS vs OPEN DATA WHAT DOES IT MEAN?

Free online access to scientific publications

Open Data to research data for 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



EUROPA > EU Open Data Portal > Home

Home | Data | Applications | Linked data | Visualisations > | Developers' corner | About

The European Union Open Data Portal (EU ODP) gives you access to open data published by EU institutions and bodies. All the data you can find via this catalogue are free to use and reuse for commercial or non-commercial purposes.

Search for metadata using our SPARQL endpoint query editor or access the API.

Discover our datasets | View datasets by subject | View all datasets | View all publishers

# 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.



[About](#) [Data Hubs](#) [Related resources](#) [Our partners](#) [Submit data](#)

[Sequences](#) [Expression](#) [Proteins](#) [Structures](#) [Compounds](#) [Targets](#) [Literature](#)

Accelerating research through data sharing



### Sequences →

Raw and assembled sequences related to the COVID-19 outbreak, including outbreak isolates and records relating to coronavirus biology. Includes extensive

### Expression data →

Gene and protein expression data of human genes implicated in the virus infection of the host cells. Identifying cell types and genes with highest expression

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## 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 ...)

# 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](mailto: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*

# Should DRIVE do more and how?

## Next step

### What to share?

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

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

### With whom to share?

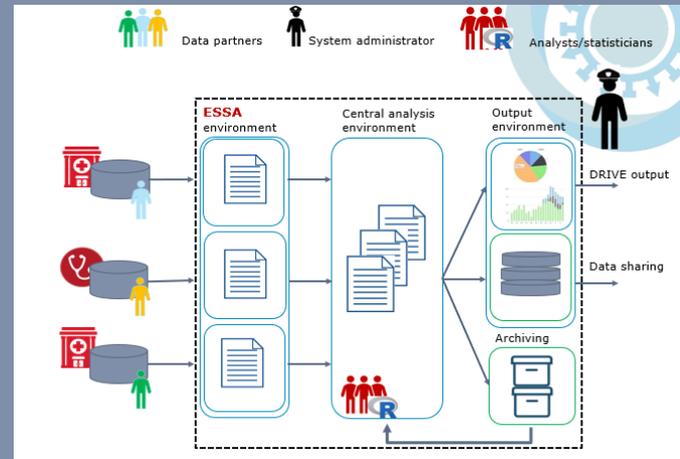
Fully open to: current sites and news sites/data contributors

Upon request if relevant research question to any third party including industry

### 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)*



To be defined

# DRIVE: Upon request model

For non DRIVE data contributors

Consensus based on guiding principles

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)

 <https://www.drive-eu.org/>

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)

**GO**

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