Characterizing Vaccine Adverse Events in COVID-19 patients across the OHDSI network

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Background

Primary focus in the initial stages of the pandemic was on **saving lives** and **preventing new infections**

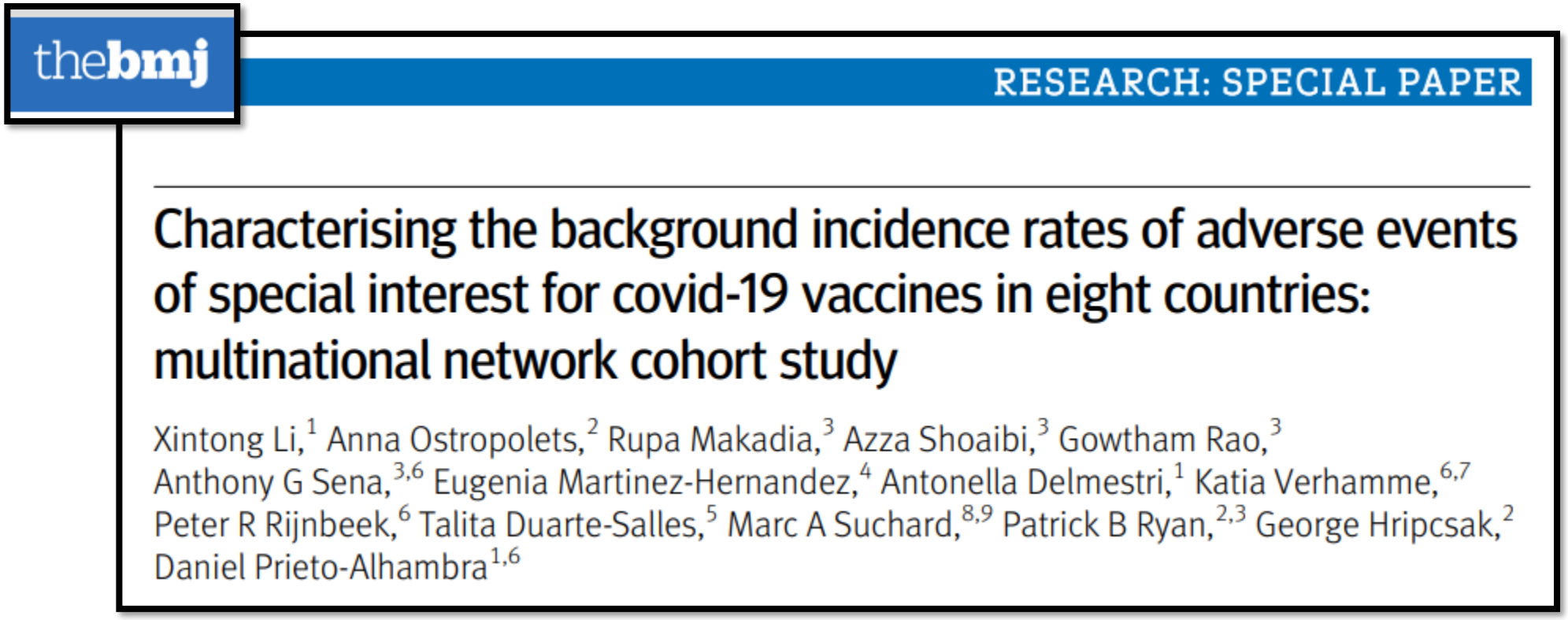
Adverse Events of Special Interest (AESI)

- Acute myocardial infarction (MI)
- Anaphylaxis
- Appendicitis
- Bell's palsy
- Deep vein thrombosis (DVT)
- Encephalomyelitis
- Guillain-Barre syndrome (GBS)
- Hemorrhagic stroke
- Non-hemorrhagic stroke
- Immune thrombocytopenia
- Myocarditis/pericarditis
- Narcolepsy
- Pulmonary embolism (PE)
- Transverse myelitis
- Disseminated intravascular coagulation

The FDA Center for Biologics Evaluation and Research prioritized a list of outcomes

- Center for Biologics Evaluation and Research Office of Biostatistics and Epidemiology. CBER Surveillance Program Background Rates of Adverse Events of Special Interest for COVID-19 Vaccine Safety Monitoring Protocol. https://www.bestinitiative.org/wp-content/ uploads/2021/02/C19-Vaccine-Safety-AESI-Background-RateProtocol-FINAL-2020.pdf (accessed 11 Mar 2021)
- bc-coordinator. Priority list of adverse events of special interest: COVID-19. 2020. https://brightoncollaboration.us/priority-list-aesicovid/ (accessed 11 Mar 2021).

Background



https://github.com/ohdsi-studies/Covid19VaccineAesiIncidenceCharacterization

Background

The Observational Health Data Sciences and Informatics (OHDSI) community carried out a population-based network study using observational data from **26 databases** across **11 countries** to explore the **incidence rate (IR) of Adverse Events of Special Interest (AESIs) among people who had COVID-19**, as compared to a pre-pandemic background population .

The Study

- **Objective:** Quantify the occurrence of AESIs in subjects with COVID-19 overall and across specific age and sex groups.

- It is relevant to know how often these AESIs occur amongst patients who suffer the condition vaccines aim to prevent to assess the benefit risk profile of the vaccine.

- Protocol: https://ohdsi-studies.github.io/Covid19SubjectsAesiIncidenceRate/Protocol.html

Public Protocol

1 List of Abbreviations
2 Responsible Parties
3 Amendments and Updates
4 Milestones
5 Rationale and Background
6 Study Objectives
7 Research Methods
8 Strengths and Limitations
9 Protection of Human Subjects
10 Management and Reporting of Adverse Events and Adverse Reactions
11 Plans for Disseminating and Communicating Study Results
References
Appendix
A Target Cohort Definitions

RESEARCH PROTOCOL

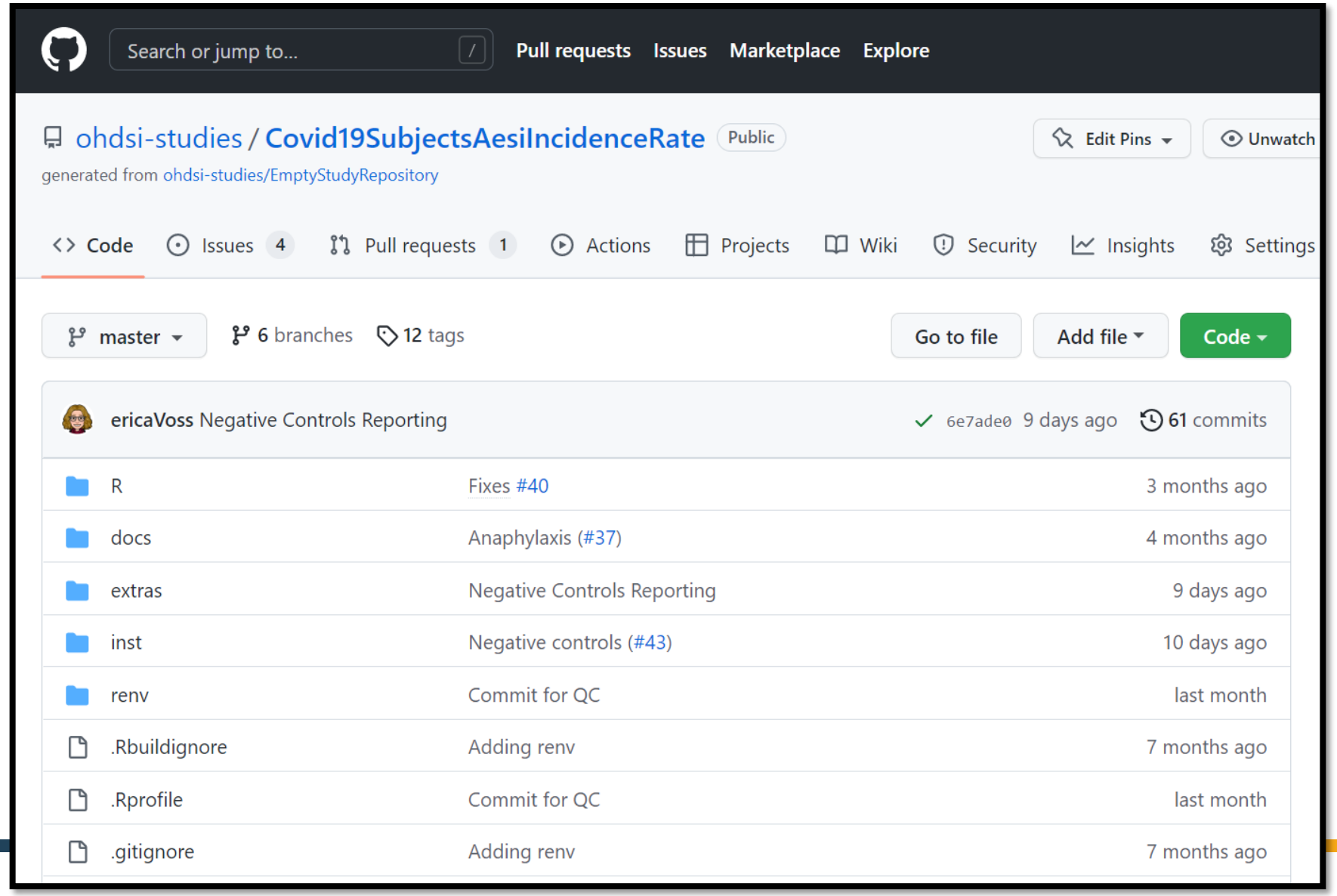
Adverse Events of Special Interest within COVID-19 Subjects

Version: 1.0.1

1 List of Abbreviations

AESI	adverse events of special interest
CCAE	IBM MarketScan(R) Commercial Claims and Encounters
CDM	Common Data Model
COVID-19	COronaVIrus Disease 2019
CPRD	Clinical Practice Research Datalink
CUIMC	Columbia University Irving Medical Center
DA	Disease Analyzer
EHR	Electronic Health Record

Public Code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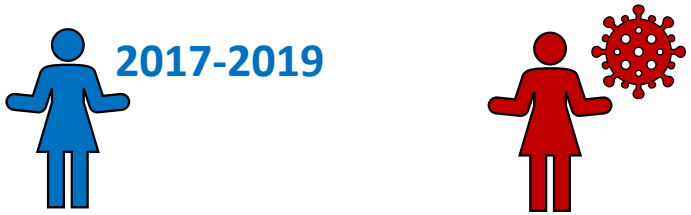
61 commits
R Fixes #40 3 months ago
docs Anaphylaxis (#37) 4 months ago
extras Negative Controls Reporting 9 days ago
inst Negative controls (#43) 10 days ago
renv Commit for QC last month
.Rbuildignore Adding renv 7 months ago
.Rprofile Commit for QC last month
.gitignore Adding renv 7 months ago

Design

- Retrospective cohort study
- Target Cohorts:
  - pre-pandemic background population (2017-2019)
  - First COVID-19 Event (positive test OR diagnosis)



- Outcome Cohorts:
  - AESIs
- Population Subgroups: age and sex
- Time at Risk: 90-days
- Outputs: Counts, Incidence Rates and Incidence Proportions of Outcomes

2017-2019

TARGET COHORT

Cohort #566 *(Read only)*

created by ryan@ohdsi.org on 2021-11-16 14:43

[COVID AESI] persons at risk at start of year 2017-2019 with 365d prior observation

Definition | Concept Sets | Generation | Samples | Reporting | Export | Versions | Messages 3

Initial Event Cohort

People having any of the following:

- an observation period
  - using specified period: starting on 2017-01-01 and ending on 2017-01-01

    Note: only observation periods that encompass the start and end dates will be used.
- an observation period
  - using specified period: starting on 2018-01-01 and ending on 2018-01-01

    Note: only observation periods that encompass the start and end dates will be used.
- an observation period
  - using specified period: starting on 2019-01-01 and ending on 2019-01-01

    Note: only observation periods that encompass the start and end dates will be used.

with continuous observation of at least 365 days prior and 0 days after event index date, and limit initial events to: **all events per person.**

Limit qualifying cohort to: **all events per person.**

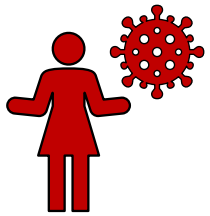
End Date Strategy

Date Offset Exit Criteria

This cohort definition end date will be the index event's start date plus 0 days

Cohort Collapse Strategy:

Collapse cohort by era with a gap size of 0 days



TARGET COHORT

Cohort #563 *(Read only)*

created by ryan@ohdsi.org on 2021-11-02 11:34

[COVID AESI] Persons with earliest COVID event based on positive test or diagnosis without neg test

Definition | Concept Sets | Generation | Samples | Reporting | Export | Versions | Messages 6

Initial Event Cohort

People having any of the following:

- a measurement of SARS-CoV-2 test[2]
  - occurrence start is: after 2019-12-01
  - value as concept is any of: Detected, Detected, Positive, Positive, Present, Present
- a condition occurrence of COVID-19[1]
  - occurrence start is: after 2019-12-01

  Having any of the following criteria:
    - exactly 0 occurrences of: a measurement of SARS-CoV-2 test[2]
      - value as concept is any of: Negative, Not detected, Not detected in pooled specimen, Absent, Negative, Not detected, Absent

    where event starts between 0 days Before and 3 days After index start date

with continuous observation of at least 0 days prior and 0 days after event index date, and limit initial events to: **earliest event per person.**

Inclusion Rules

Inclusion Criteria #(1): Continuous Observation of at least 365d
Having all of the following criteria:

- at least 1 occurrences of: an observation period

  where event starts between All days Before and 365 days Before index start date and event ends between 0 days After and All days After index start date

Inclusion Criteria #(2): No COVID-19/SARS-CoV-2 Tests Prior to Index
Having all of the following criteria:

- exactly 0 occurrences of: a measurement of SARS-CoV-2 test[2]
  - value as concept is any of: Detected, Detected, Positive, Positive, Present, Present

  where event starts between All days Before and 1 days Before index start date
- and exactly 0 occurrences of: a condition occurrence of COVID-19[1]

  Having any of the following criteria:
    - exactly 0 occurrences of: a measurement of SARS-CoV-2 test[2]
      - value as concept is any of: Negative, Not detected, Not detected in pooled specimen, Absent, Negative, Not detected, Absent

    where event starts between All days Before and 3 days After index start date

  where event starts between All days Before and 1 days Before index start date

Limit qualifying cohort to: **earliest event per person.**

End Date Strategy

Date Offset Exit Criteria

This cohort definition end date will be the index event's start date plus 3 days

Cohort Collapse Strategy:

Collapse cohort by era with a gap size of 0 days

Outcomes (AESIs)

- Acute myocardial infarction (MI)
- Anaphylaxis
- Appendicitis
- Bell's palsy
- Deep vein thrombosis (DVT)
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- Guillain-Barre syndrome (GBS)
- Hemorrhagic stroke
- Non-hemorrhagic stroke
- Immune thrombocytopenia
- Myocarditis/pericarditis
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- Pulmonary embolism (PE)
- Transverse myelitis
- Disseminated intravascular coagulation
- Thrombosis with Thrombocytopenia (TWT)**

Outcomes (AESIs)

- Acute myocardial infarction (MI)
- Anap
- Appe
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- Deep
- Ence
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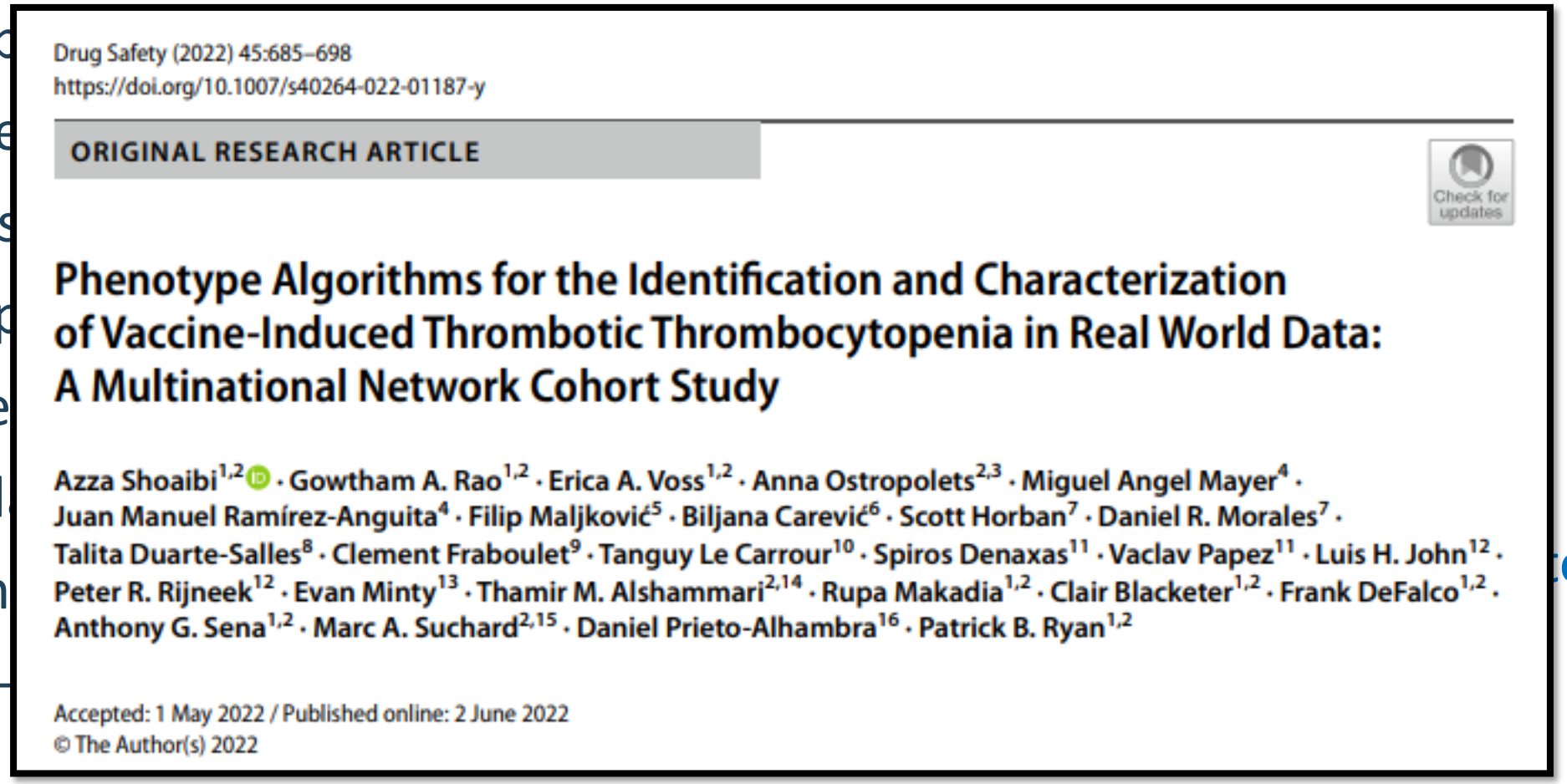
- Hem
- Non-
- Immune thrombocytopenia



Drug Safety (2022) 45:685–698
https://doi.org/10.1007/s40264-022-01187-y

ORIGINAL RESEARCH ARTICLE

Check for updates

Phenotype Algorithms for the Identification and Characterization of Vaccine-Induced Thrombotic Thrombocytopenia in Real World Data: A Multinational Network Cohort Study

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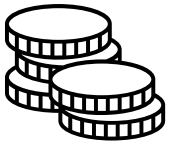
Accepted: 1 May 2022 / Published online: 2 June 2022

Methods: Data Sources

- Data were obtained from 26 databases

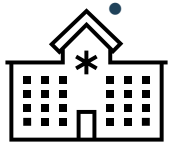
- These databases represent 11 countries:
  - Belgium
  - Estonia
  - France
  - Germany
  - Japan
  - The Netherlands
  - Serbia
  - Spain
  - Turkey
  - United Kingdom (UK)
  - United States of America (US)

Methods: Data Sources

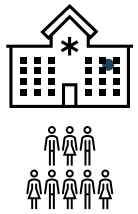


- **Administrative Claims:**
IBM® MarketScan® Commercial Claims and Encounters Database (IBM_CCAE); IBM® MarketScan® Multi-State Medicaid Database (IBM_MDCD); IBM® MarketScan® Medicare Supplemental and Coordination of Benefits Database (IBM_MDCR); IQVIA LRxDX Open Claims (IQVIA_OPENCLAIMS); IQVIA Pharmetrics (IQVIA_PHARMETRICS); JMDC; Optum De-Identified Clinformatics® Data Mart Database - Socio-Economic Status (SES) (OPTUM_SES); and University of Tartu (U_OF_TARTU).

- **General Practitioner:**
Clinical Practice Research Datalink AURUM (CPRD_AURUM); Integrated Primary Care Information (IPCI); IQVIA® Disease Analyzer France (IQVIA_FRANCE_DA); IQVIA® Disease Analyzer Germany (IQVIA_GERMAN_DA); and The Information System for Research on Primary Care (SIDIAP).



- **Electronic Health Records:**
Health Data Warehouse of Assistance Publique - Hopitaux de Marseille (APHM); University of Colorado Anschutz Medical Campus- Health Data Compass (CU_AMC); Columbia University Irving Medical Center (CUIMC); Fundación para la Investigación e Innovación Biosanitaria en Atención Primaria COVID19 (FIIBAP); Health Informatics Centre (HIC); Parc de Salut Mar Barcelona Information System (IMASIS); Istanbul Faculty of Medicine, Istanbul University (IU); Medaman Hospital Data (MHD); Optum® de-identified Electronic Health Record Dataset (OPTUM_EHR); STAnford medicine Research data Repository (STARR); University Clinical Center of Serbia (UCCS); and University of California Health Data Warehouse (UCHEALTHDW).

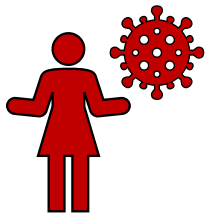


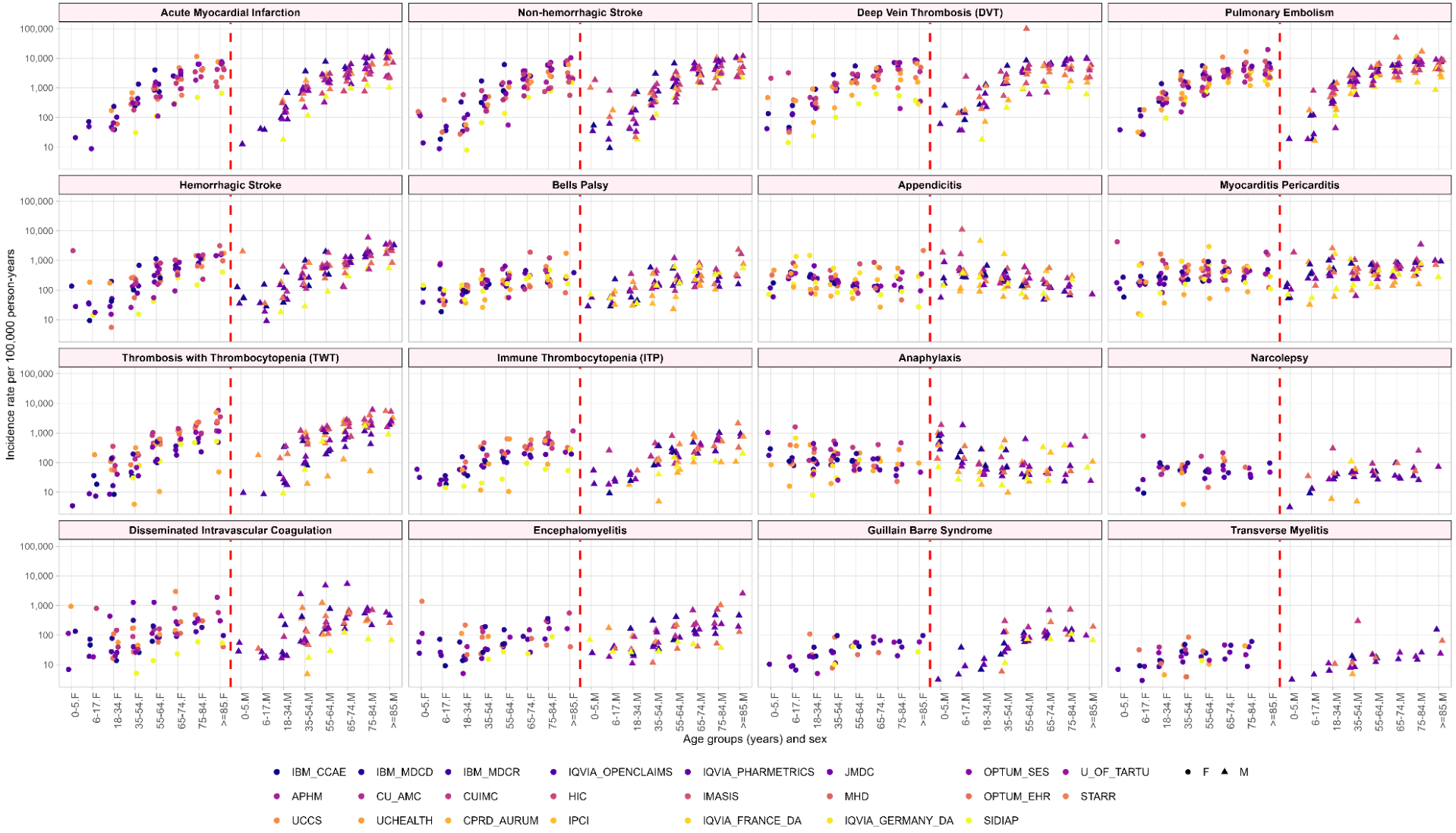
Electronic Health Records with Registry:
UK Biobank (UK_BIOBANK).

Name	Country	Data Provenance	Dates Covered YYYY/MM	Total Persons	% F	Ages Covered Mean Age (IQR)	Subjects with COVID-19 #	Pre-Pandemic Background Population #	Measure-ments With Values
APHM	FR	EHR	1998/11-2021/07	2,465,265	51.9	40 (21-60)	11,431	673,031	N
CPRD_AURUM	UK	GP	1995/01-2021/03	39,879,547	51.8	31 (18-44)	587,886	14,094,032	Y
CU_AMC	US	EHR	2011/01-2022/04	4,795,392	54.0	39 (22-56)	72,648	830,579	Y
CUIMC	US	EHR	1985/03-2021/08	6,808,470	55.8	38 (21-56)	28,044	1,197,983	Y
FIIBAP*	ES	EHR	2001/03-2021/10	292,305	54.7	41 (23-58)	7,138	78	N
HIC	SC	EHR	2005/01-2021/12	1,254,464	50.4	45 (28-66)	11,813	885,236	Y
IBM_CCAE	US	Claims	2000/01-2021/07	159,440,276	51.1	31 (17-46)	983,089	23,483,191	N
IBM_MDCD	US	Claims	2006/01-2020/12	32,806,887	56.2	24 (5-38)	196,997	11,810,505	N
IBM_MDCR	US	Claims	2000/01-2021/07	10,356,249	55.3	72 (65-77)	41,542	1,467,963	N
IMASIS	ES	EHR	1990/02-2021/07	976,524	47.4	38 (23-54)	9,330	198,012	Y
IPCI	NL	GP	2006/01-2021/06	2,529,355	51.2	37 (18-55)	91,759	1,329,674	N
IQVIA_FRANCE_DA	FR	GP	2016/07-2021/06	3,767,012	52.3	38 (18-56)	2,859	1,394,912	N
IQVIA_GERMANY_DA	DE	GP	2011/04-2021/03	30,780,239	55.7	44 (25-62)	45,508	9,040,531	N
IQVIA_OPENCLAIMS	US	Claims	2000/01-2021/10	306,000,000	52.6	34 (14-52)	17,848,443	306,000,000	N
IQVIA_PHARMETRICS	US	Claims	2013/01-2021/09	166,422,594	50.6	38 (19-50)	1,593,578	46,947,246	N
IU	TR	EHR	2018/01-2021/10	899,515	53.0	35 (18-52)	6,194	619	Y
JMDC	JP	Claims	2005/01-2021/03	12,541,088	48.6	32 (19-46)	17,564	6,680,196	N
MHD	BE	EHR	2015/07-2021/12	117,131	50.9	52 (29-70)	203	23,754	N
OPTUM_EHR	US	EHR	2007/01-2021/03	99,454,715	53.3	37 (19-56)	693,334	41,281,147	Y
OPTUM_SES	US	Claims	2000/05-2021/06	90,285,937	50.5	36 (19-52)	899,986	17,212,611	Y
SIDIAP	ES	GP	2003/01-2021/06	8,022,374	50.1	35 (17-51)	495,237	5,934,449	Y
STARR	US	EHR	2008/01-2022/04	3,475,673	53.6	36 (18-54)	31,928	1,118,549	Y
U_OF_TARTU†	EE	Claims	2021/01-2021/02	386,557	53.2	39 (21-57)	84,957	376,842	N
UCCS	RS	EHR	2018/10-2021/03	823,962	54.1	51 (35-67)	16,764	49,643	N
UCHDW*	US	EHR	2012/01-2022/05	316,119	53.8	37 (12-54)	61,037	240,831	Y
UK_BIOBANK	UK	EHR + Registry	1970/02-2020/07	502,504	54.4	34 (25-43)	1,717	458,889	Y
Total	-	-	-	*945,520,607*	-	-	*23,840,986*	*492,730,503*	-

* COVID only subset, † COVID + Controls

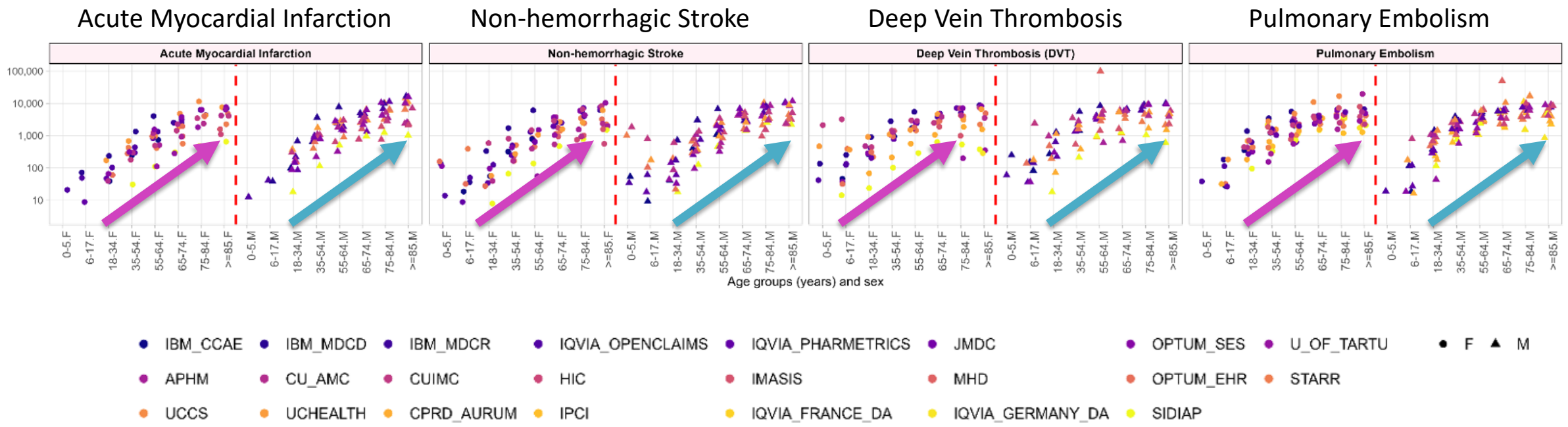
Age-Sex Stratified Incidence Rates per Database





Age-Sex Stratified Incidence Rates per Database

- Some AESIs clearly increase in frequency with age



Age-Sex Stratified Incidence Rates per Database

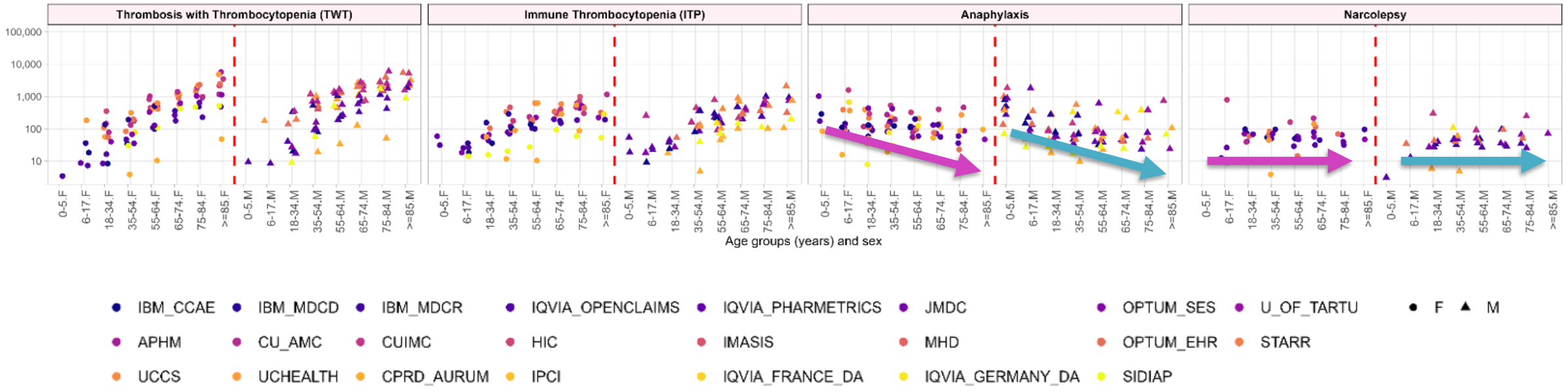
- Others have less clear or even opposite trend

Thrombosis w/ Thrombocytopenia

Immune Thrombocytopenia

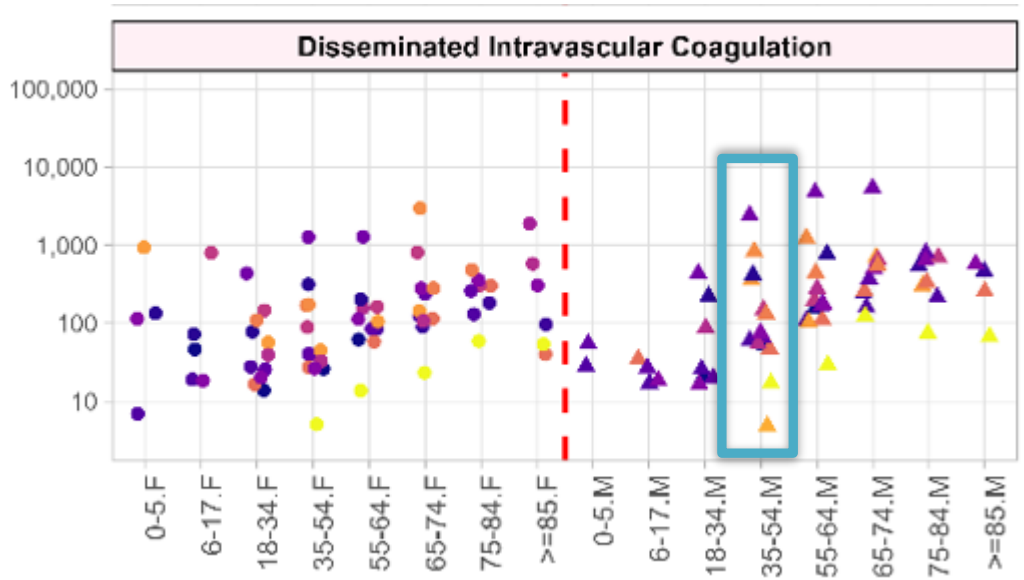
Anaphylaxis

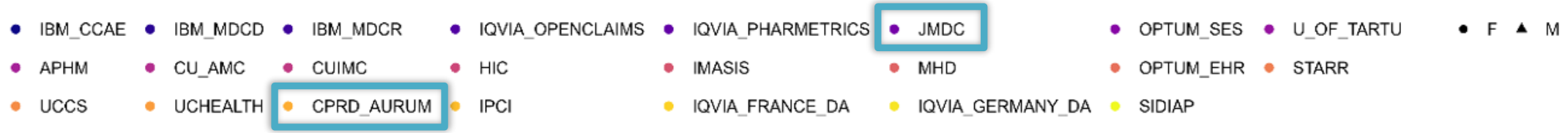
Narcolepsy



Age-Sex Stratified Incidence Rates per Database

- Heterogeneity between databases





Pooled Estimated Age and Sex Stratified Incidence Rates Per 100,000 person years (with 95% prediction intervals), calculated from meta-analyses

Outcome by Sex	0-5 Years	6-17 Years	18-34 Years	35-54 Years	55-64 Years	65-74 Years	75-84 Years	>=85 Years
Acute Myocardial Infarction (AMI)								
Female	6 (0 to 250)	3 (0 to 40)	11 (3 to 41)	53 (14 to 211)	151 (41 to 550)	237 (94 to 600)	532 (241 to 1172)	996 (241 to 4111)
Male	6 (0 to 219)	3 (0 to 19)	18 (6 to 52)	152 (54 to 432)	400 (166 to 965)	539 (242 to 1202)	789 (354 to 1758)	1306 (292 to 5847)
Non-hemorrhagic Stroke								
Female	12 (2 to 87)	6 (2 to 21)	19 (6 to 61)	67 (16 to 278)	152 (36 to 643)	274 (95 to 792)	647 (285 to 1472)	1412 (322 to 6185)
Male	12 (3 to 48)	8 (2 to 28)	17 (5 to 59)	93 (29 to 301)	252 (83 to 769)	417 (173 to 1008)	774 (334 to 1791)	1246 (243 to 6382)
Deep Vein Thrombosis (DVT)								
Female	10 (2 to 58)	8 (3 to 25)	52 (19 to 141)	91 (33 to 251)	146 (55 to 393)	224 (90 to 560)	387 (169 to 888)	378 (82 to 1753)
Male	11 (2 to 57)	10 (3 to 30)	48 (17 to 134)	107 (40 to 289)	251 (105 to 602)	302 (124 to 735)	437 (188 to 1019)	408 (81 to 2046)
Pulmonary Embolism (PE)								
Female	5 (0 to 111)	3 (1 to 11)	43 (16 to 114)	90 (32 to 253)	155 (59 to 407)	238 (120 to 475)	430 (227 to 815)	492 (161 to 1496)
Male	5 (0 to 118)	3 (1 to 13)	29 (10 to 85)	98 (37 to 256)	199 (90 to 439)	280 (143 to 549)	409 (205 to 819)	419 (124 to 1424)
Hemorrhagic Stroke								
Female	17 (2 to 118)	7 (2 to 23)	15 (4 to 55)	32 (10 to 103)	64 (22 to 184)	88 (33 to 232)	196 (84 to 457)	363 (84 to 1564)
Male	14 (3 to 65)	10 (3 to 37)	21 (6 to 66)	44 (15 to 124)	94 (35 to 253)	128 (55 to 298)	272 (121 to 612)	403 (85 to 1901)
Bell's Palsy								
Female	19 (7 to 53)	23 (11 to 47)	44 (20 to 96)	62 (25 to 158)	79 (32 to 198)	82 (30 to 224)	100 (33 to 301)	97 (29 to 321)
Male	18 (6 to 54)	20 (10 to 42)	42 (19 to 92)	64 (26 to 157)	84 (34 to 209)	93 (35 to 244)	100 (33 to 302)	106 (31 to 365)
Appendicitis								
Female	33 (13 to 82)	161 (71 to 363)	140 (69 to 286)	89 (44 to 178)	76 (38 to 153)	55 (26 to 116)	46 (20 to 105)	40 (10 to 171)
Male	37 (18 to 77)	211 (119 to 371)	152 (80 to 287)	92 (48 to 177)	70 (35 to 140)	59 (28 to 121)	49 (23 to 105)	47 (12 to 189)
Myocarditis Pericarditis								
Female	9 (1 to 68)	9 (2 to 38)	20 (6 to 66)	29 (10 to 85)	39 (14 to 108)	41 (15 to 112)	49 (18 to 133)	43 (6 to 295)
Male	9 (1 to 66)	11 (4 to 36)	40 (14 to 112)	44 (15 to 132)	53 (18 to 155)	57 (21 to 154)	64 (20 to 205)	51 (8 to 338)
Thrombosis with Thrombocytopenia (TWT)								
Female	7 (0 to 779)	3 (0 to 170)	7 (1 to 91)	12 (1 to 146)	26 (2 to 281)	37 (3 to 410)	80 (8 to 810)	174 (43 to 701)
Male	6 (0 to 328)	3 (0 to 140)	7 (0 to 148)	23 (1 to 422)	54 (4 to 737)	81 (6 to 1069)	146 (14 to 1568)	320 (88 to 1155)
Immune Thrombocytopenia (ITP)								
Female	18 (6 to 52)	12 (5 to 30)	23 (7 to 73)	23 (8 to 71)	30 (11 to 87)	36 (13 to 101)	50 (18 to 141)	45 (11 to 185)
Male	20 (8 to 52)	11 (4 to 31)	11 (3 to 37)	17 (5 to 56)	29 (10 to 89)	45 (15 to 137)	76 (26 to 218)	85 (22 to 334)
Anaphylaxis								
Female	85 (7 to 1002)	66 (3 to 1556)	47 (11 to 195)	41 (11 to 146)	38 (9 to 154)	30 (9 to 95)	25 (8 to 78)	15 (2 to 99)
Male	124 (9 to 1628)	72 (2 to 3305)	31 (7 to 134)	26 (6 to 106)	28 (5 to 168)	25 (6 to 107)	17 (6 to 44)	12 (4 to 35)
Narcolepsy								
Female	5 (0 to 386)	8 (3 to 27)	28 (8 to 95)	23 (7 to 80)	19 (6 to 60)	15 (5 to 44)	16 (5 to 49)	15 (3 to 81)
Male	5 (0 to 179)	8 (2 to 26)	20 (6 to 61)	19 (6 to 61)	18 (6 to 56)	15 (5 to 45)	18 (6 to 55)	21 (5 to 94)
Disseminated Intravascular Coagulation (DIC)								
Female	9 (0 to 397)	4 (0 to 82)	8 (0 to 141)	9 (1 to 102)	13 (2 to 94)	14 (3 to 77)	19 (5 to 72)	25 (4 to 156)
Male	9 (0 to 369)	5 (0 to 109)	5 (0 to 51)	11 (1 to 106)	19 (2 to 161)	21 (3 to 165)	28 (7 to 117)	34 (8 to 145)
Encephalomyelitis								
Female	10 (2 to 68)	9 (2 to 54)	7 (1 to 37)	8 (1 to 45)	13 (3 to 64)	14 (4 to 48)	16 (4 to 59)	25 (4 to 179)
Male	9 (2 to 57)	10 (2 to 57)	8 (2 to 39)	8 (2 to 37)	15 (3 to 66)	15 (4 to 53)	22 (5 to 95)	29 (6 to 151)
Guillain-Barré Syndrome (GBS)								
Female	7 (0 to 507)	3 (0 to 43)	4 (1 to 16)	4 (1 to 15)	6 (2 to 24)	7 (2 to 28)	9 (3 to 32)	16 (2 to 137)
Male	8 (0 to 275)	3 (0 to 20)	3 (1 to 11)	5 (2 to 16)	9 (3 to 26)	10 (4 to 28)	16 (5 to 53)	19 (5 to 65)
Transverse Myelitis								
Female	4 (0 to 290)	2 (0 to 20)	5 (1 to 16)	7 (2 to 24)	7 (3 to 20)	7 (3 to 20)	5 (2 to 15)	7 (0 to 198)
Male	4 (0 to 283)	2 (0 to 18)	3 (1 to 8)	4 (1 to 15)	6 (2 to 20)	5 (2 to 13)	6 (1 to 22)	7 (1 to 35)

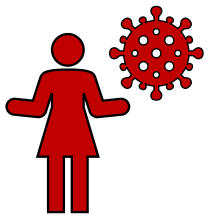
2017-2019

CIOMS Frequency Classification
Very Rare (<1/10000)
Rare (>=10000 to <1/1000)
Uncommon (>= 1/1000 to <1/100)
Common (>= 1/100 to <1/10)
Very Common (>=1 /10)

CIOMS: Council of International Organizations of Medical Sciences

Pooled Estimated Age and Sex Stratified Incidence Rates Per 100,000 person years (with 95% prediction intervals), calculated from meta-analyses

Outcome by Sex	0-5 Years	6-17 Years	18-34 Years	35-54 Years	55-64 Years	65-74 Years	75-84 Years	>=85 Years
Acute Myocardial Infarction								
Female	527 (2 to 116345)	151 (5 to 4281)	84 (28 to 253)	335 (123 to 910)	940 (374 to 2365)	2047 (1044 to 4014)	3940 (1969 to 7882)	4960 (2090 to 11772)
Male	469 (2 to 121380)	139 (4 to 5421)	167 (44 to 639)	827 (333 to 2053)	1991 (954 to 4153)	3526 (1945 to 6391)	5721 (2717 to 12046)	8198 (2782 to 24155)
Non-hemorrhagic Stroke								
Female	552 (3 to 95794)	153 (6 to 3663)	96 (21 to 441)	356 (105 to 1209)	839 (223 to 3156)	1790 (829 to 3866)	3723 (1677 to 8265)	4928 (1974 to 12303)
Male	547 (4 to 79312)	162 (8 to 3148)	121 (16 to 924)	575 (155 to 2135)	1422 (476 to 4249)	2965 (1532 to 5739)	5009 (2421 to 10361)	6524 (2225 to 19132)
Deep Vein Thrombosis (DVT)								
Female	478 (5 to 44031)	245 (25 to 2399)	287 (97 to 847)	817 (337 to 1979)	1638 (743 to 3610)	2839 (1549 to 5203)	3908 (1968 to 7763)	3781 (1467 to 9750)
Male	425 (8 to 23054)	217 (24 to 1935)	346 (81 to 1468)	1364 (490 to 3794)	2993 (1479 to 6057)	3994 (2213 to 7211)	4538 (2113 to 9750)	4504 (1789 to 11342)
Pulmonary Embolism								
Female	504 (5 to 53649)	168 (17 to 1697)	409 (124 to 1346)	1119 (493 to 2539)	2025 (1021 to 4014)	3650 (2533 to 5259)	4782 (3044 to 7515)	4718 (2353 to 9460)
Male	444 (3 to 67053)	170 (13 to 2194)	521 (109 to 2491)	1686 (652 to 4358)	3438 (2014 to 5868)	5230 (3953 to 6920)	6504 (4119 to 10269)	6480 (3914 to 10726)
Hemorrhagic Stroke								
Female	574 (3 to 101501)	145 (5 to 4607)	60 (14 to 248)	155 (41 to 590)	328 (123 to 874)	592 (295 to 1186)	935 (401 to 2178)	1175 (556 to 2482)
Male	568 (4 to 72465)	150 (7 to 3149)	109 (25 to 484)	263 (75 to 925)	550 (193 to 1567)	781 (371 to 1644)	1452 (738 to 2855)	1948 (487 to 7798)
Bell's Palsy								
Female	539 (8 to 34829)	189 (17 to 2091)	91 (59 to 143)	153 (77 to 304)	212 (98 to 457)	300 (71 to 1261)	383 (82 to 1787)	403 (65 to 2519)
Male	464 (5 to 46723)	166 (18 to 1513)	91 (35 to 236)	182 (86 to 384)	240 (87 to 666)	310 (98 to 978)	378 (73 to 1958)	648 (68 to 6176)
Appendicitis								
Female	580 (27 to 12353)	355 (175 to 719)	260 (145 to 467)	181 (100 to 326)	159 (71 to 356)	200 (57 to 700)	269 (49 to 1487)	334 (30 to 3778)
Male	561 (29 to 10808)	432 (195 to 961)	345 (153 to 780)	210 (123 to 359)	159 (86 to 292)	201 (69 to 588)	292 (47 to 1834)	450 (31 to 6580)
Myocarditis Pericarditis								
Female	650 (19 to 22601)	268 (74 to 965)	329 (76 to 1418)	290 (122 to 688)	344 (131 to 904)	383 (142 to 1037)	404 (132 to 1242)	425 (88 to 2052)
Male	529 (24 to 11794)	362 (106 to 1237)	469 (164 to 1340)	330 (147 to 742)	374 (167 to 840)	498 (208 to 1191)	709 (207 to 2423)	798 (131 to 4842)
Thrombosis with Thrombocytopenia (TWT)								
Female	457 (3 to 62013)	146 (1 to 17082)	57 (6 to 546)	116 (17 to 794)	312 (47 to 2069)	582 (84 to 4015)	964 (74 to 12496)	1476 (94 to 23167)
Male	430 (2 to 74298)	137 (1 to 21627)	89 (10 to 803)	280 (35 to 2221)	600 (80 to 4488)	1143 (135 to 9644)	1741 (146 to 20754)	2096 (173 to 25442)
Immune Thrombocytopenia (ITP)								
Female	506 (5 to 55485)	161 (4 to 6440)	67 (24 to 188)	110 (36 to 340)	189 (62 to 580)	286 (87 to 947)	452 (99 to 2058)	409 (71 to 2366)
Male	480 (4 to 59121)	150 (3 to 6553)	52 (17 to 160)	127 (45 to 361)	204 (90 to 464)	361 (122 to 1065)	517 (125 to 2145)	754 (136 to 4193)
Anaphylaxis								
Female	546 (34 to 8722)	224 (38 to 1298)	120 (57 to 252)	135 (46 to 393)	134 (39 to 457)	165 (31 to 886)	209 (15 to 2851)	299 (10 to 9177)
Male	670 (105 to 4273)	222 (40 to 1228)	90 (29 to 281)	100 (21 to 487)	101 (17 to 588)	144 (18 to 1139)	272 (7 to 10999)	430 (6 to 31495)
Narcolepsy								
Female	508 (4 to 66259)	182 (2 to 18808)	69 (29 to 163)	73 (27 to 194)	98 (15 to 621)	186 (18 to 1892)	213 (14 to 3336)	337 (7 to 16043)
Male	459 (3 to 81397)	169 (1 to 20837)	59 (16 to 220)	73 (17 to 308)	103 (15 to 710)	167 (12 to 2232)	302 (11 to 8349)	495 (10 to 25617)
Disseminated Intravascular Coagulation								
Female	509 (4 to 65261)	148 (4 to 5549)	48 (10 to 229)	91 (9 to 920)	163 (32 to 820)	302 (41 to 2226)	326 (71 to 1500)	397 (33 to 4751)
Male	452 (4 to 55867)	127 (3 to 5681)	67 (7 to 679)	164 (11 to 2349)	294 (33 to 2653)	487 (68 to 3504)	613 (82 to 4595)	536 (93 to 3076)
Encephalomyelitis								
Female	575 (4 to 93365)	145 (3 to 6015)	49 (7 to 348)	76 (12 to 503)	91 (24 to 347)	148 (31 to 713)	257 (40 to 1673)	344 (24 to 4934)
Male	495 (3 to 84065)	146 (8 to 2571)	56 (13 to 253)	85 (18 to 408)	134 (34 to 520)	180 (56 to 583)	379 (55 to 2614)	563 (43 to 7329)
Guillain Barre Syndrome								
Female	508 (2 to 133569)	131 (1 to 20989)	34 (9 to 130)	52 (9 to 292)	88 (19 to 403)	150 (22 to 1018)	181 (13 to 2611)	295 (7 to 12936)
Male	441 (2 to 96492)	126 (1 to 25674)	51 (3 to 826)	73 (11 to 473)	106 (38 to 301)	162 (44 to 591)	295 (39 to 2229)	478 (14 to 16304)
Transverse Myelitis								
Female	456 (2 to 87635)	117 (1 to 21552)	30 (4 to 206)	35 (6 to 190)	47 (10 to 231)	96 (7 to 1379)	121 (3 to 4442)	168 (2 to 12892)
Male	406 (2 to 66668)	112 (1 to 22746)	40 (1 to 1354)	41 (4 to 414)	52 (7 to 388)	89 (5 to 1743)	172 (3 to 11116)	283 (6 to 12779)



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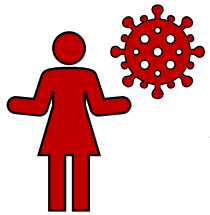
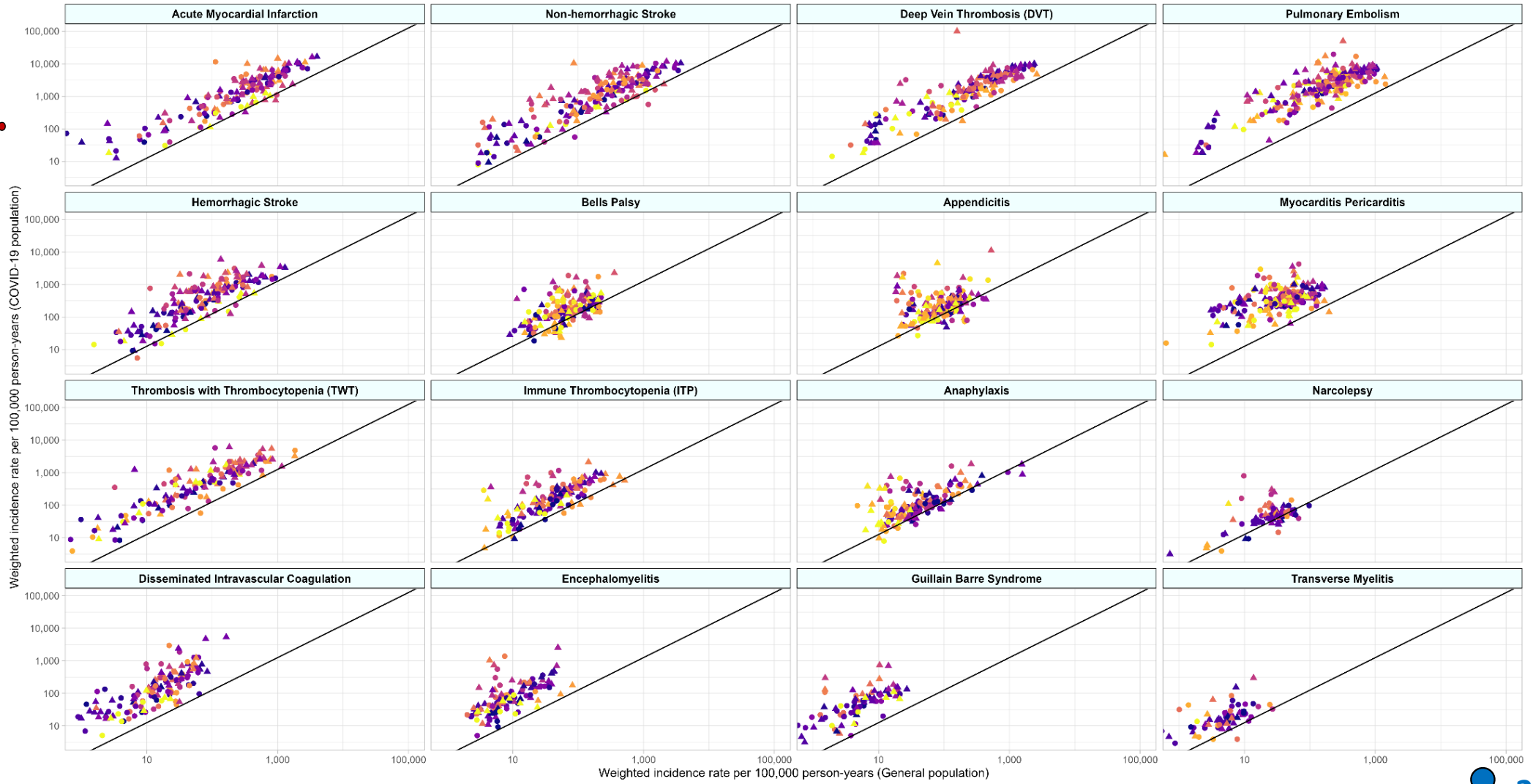
CIOMS: Council of International Organizations of Medical Sciences

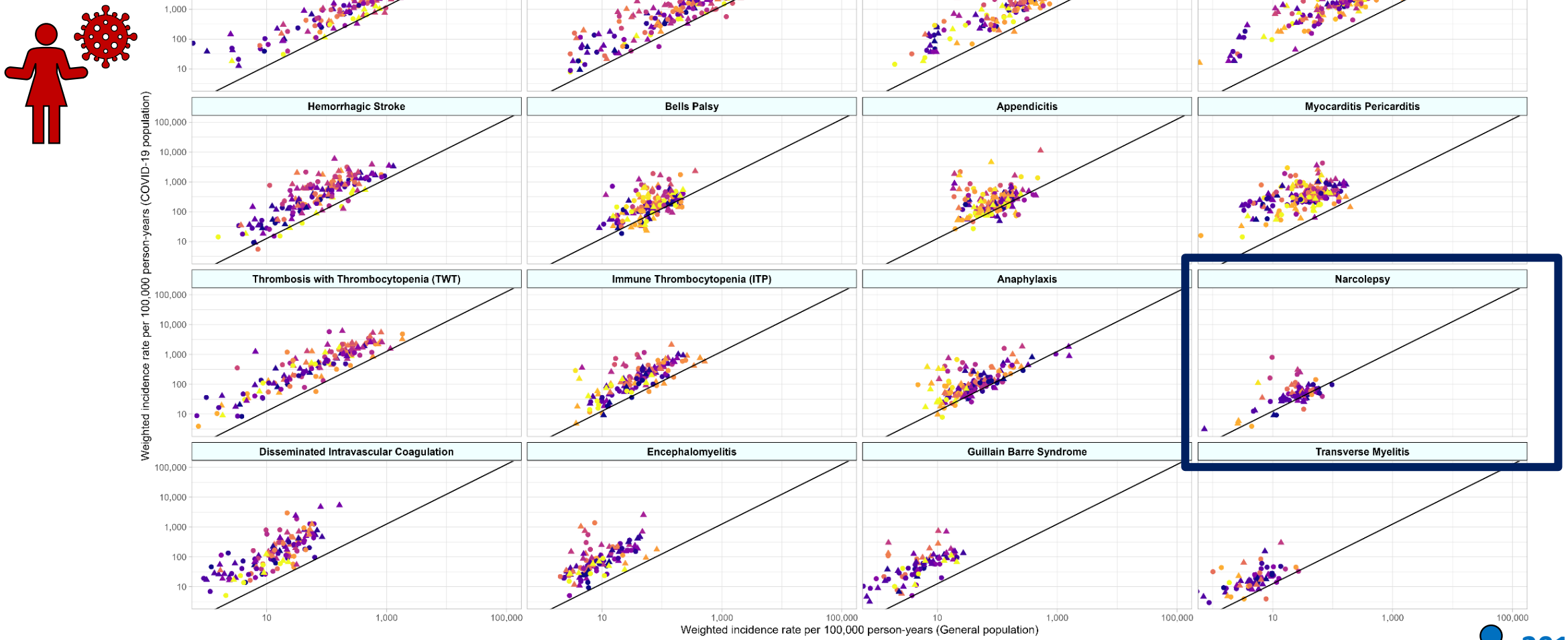
Comparing the ‘Subjects with COVID-19' Stratified Incidence Rates for AESIs to Those for ‘Pre-Pandemic Background Population’





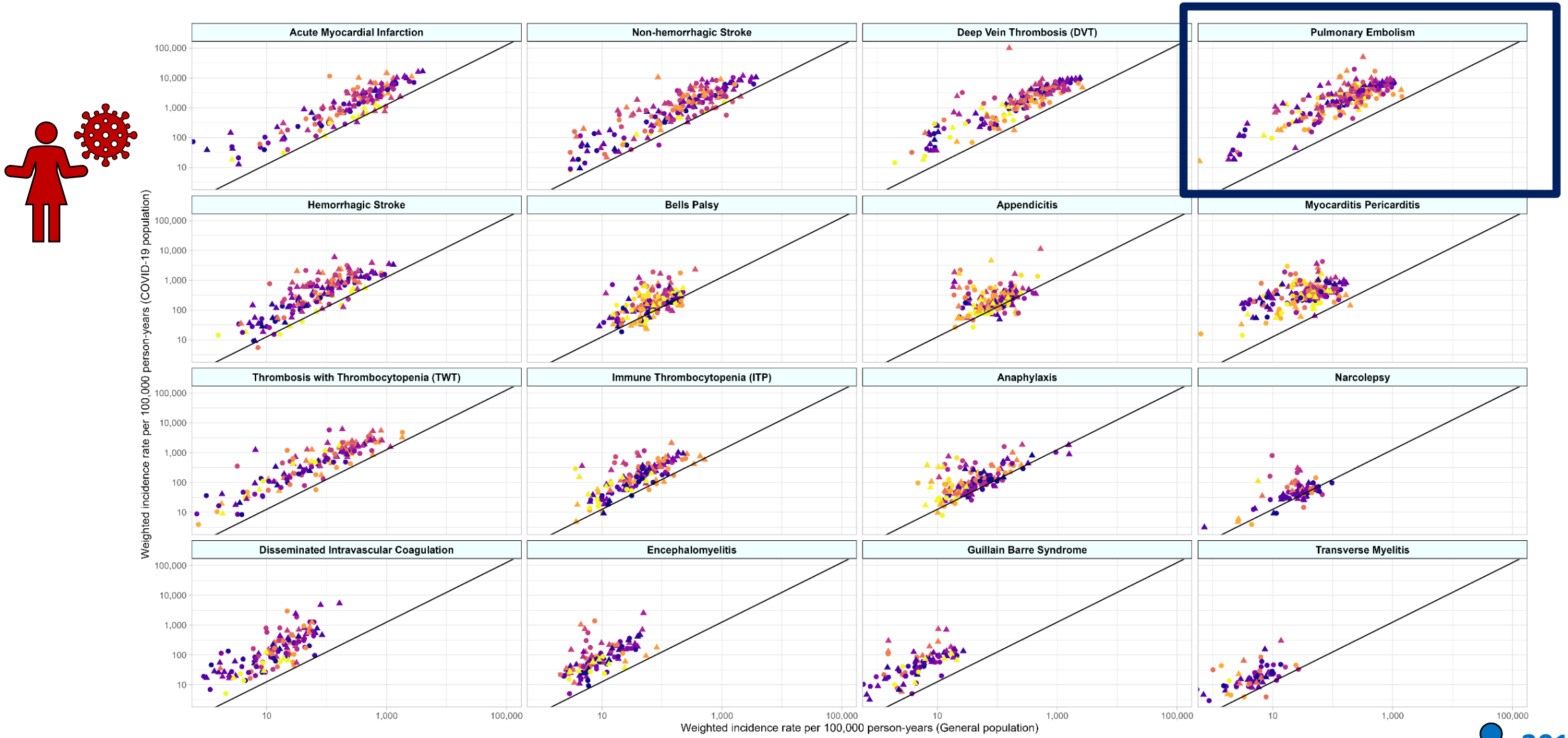
2017-2019

Comparing the ‘Subjects with COVID-19' Stratified Incidence Rates for AESIs to Those for ‘Pre-Pandemic Background Population’



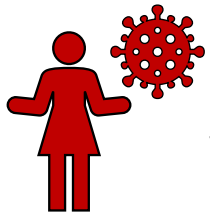
2017-2019

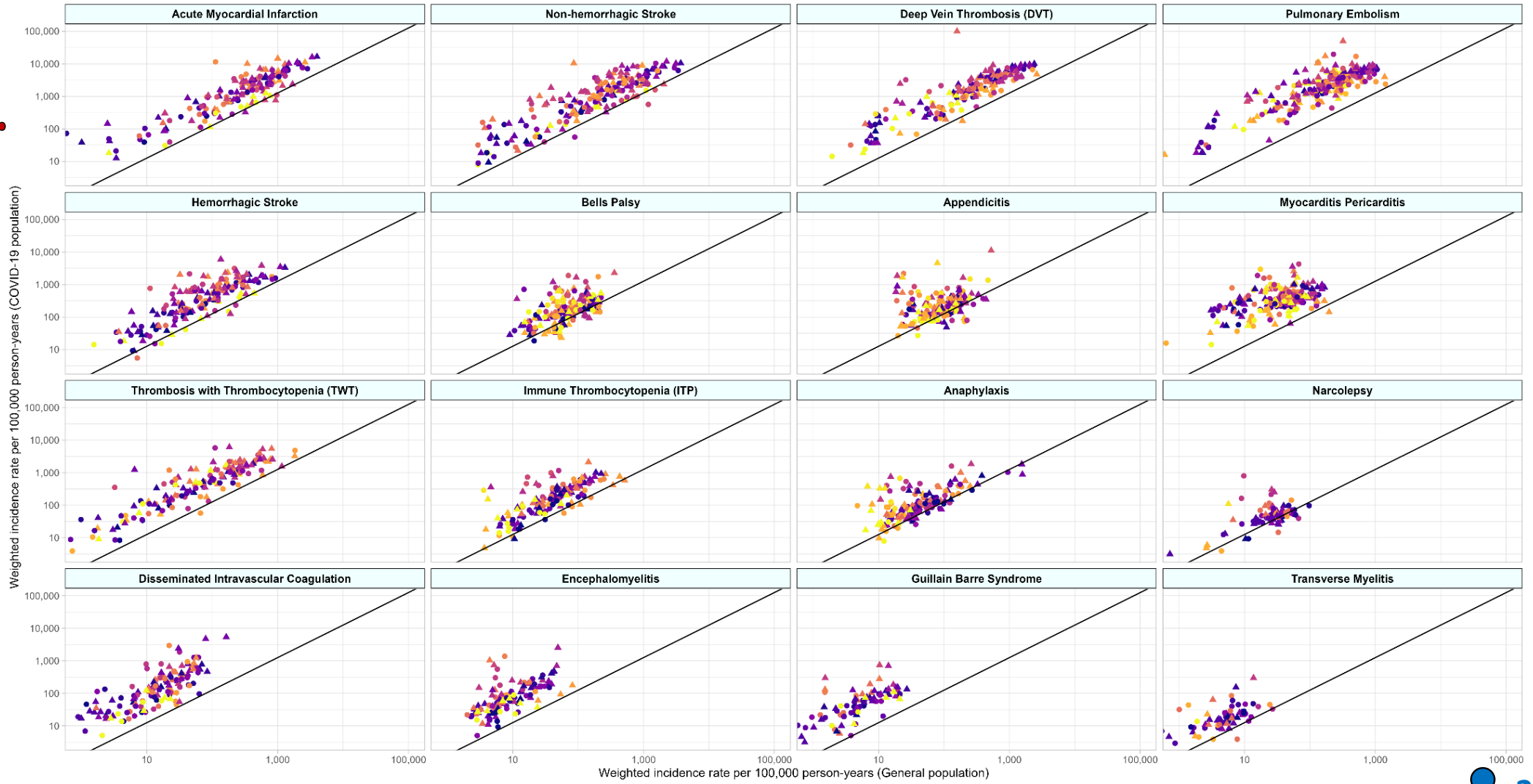
Comparing the ‘Subjects with COVID-19' Stratified Incidence Rates for AESIs to Those for ‘Pre-Pandemic Background Population’



2017-2019

Comparing the ‘Subjects with COVID-19' Stratified Incidence Rates for AESIs to Those for ‘Pre-Pandemic Background Population’

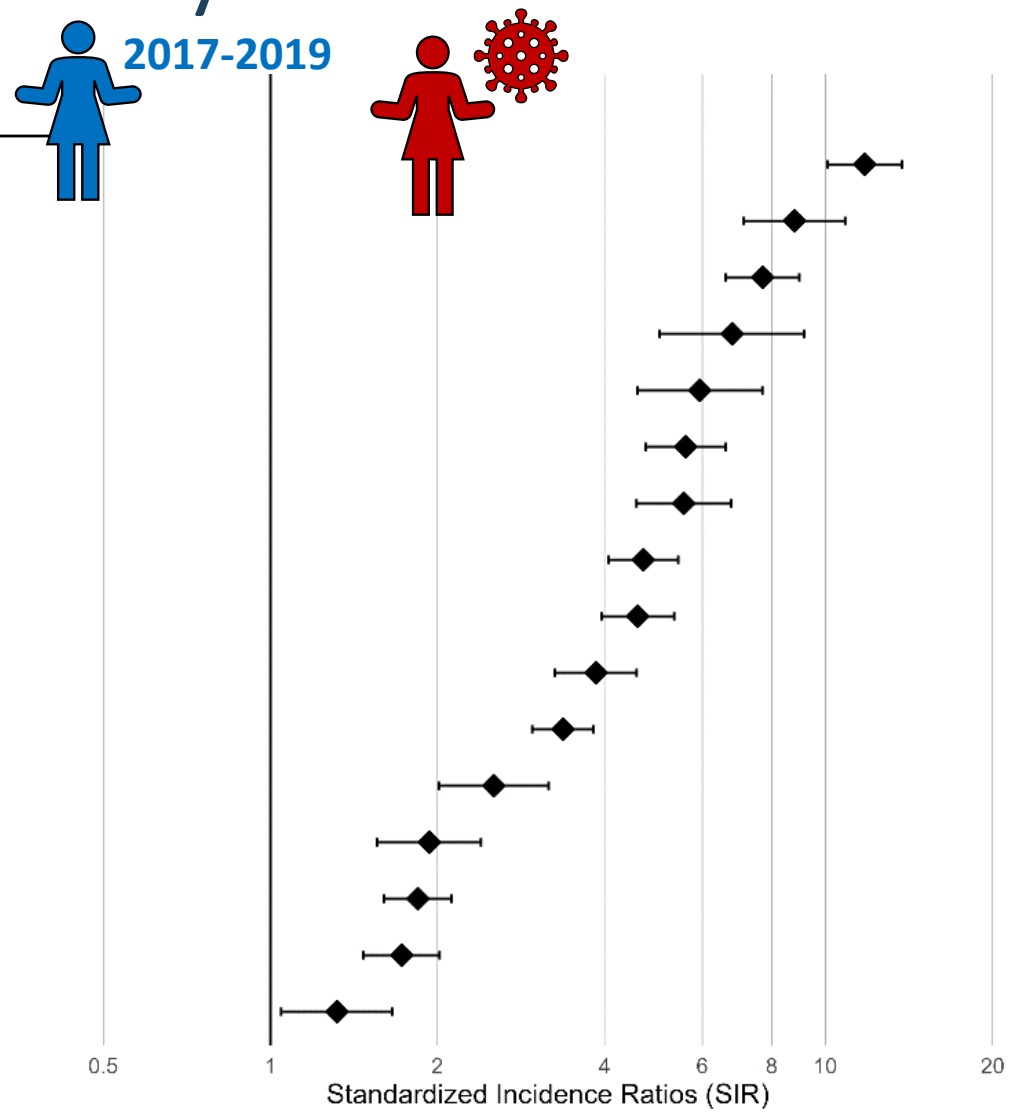




2017-2019

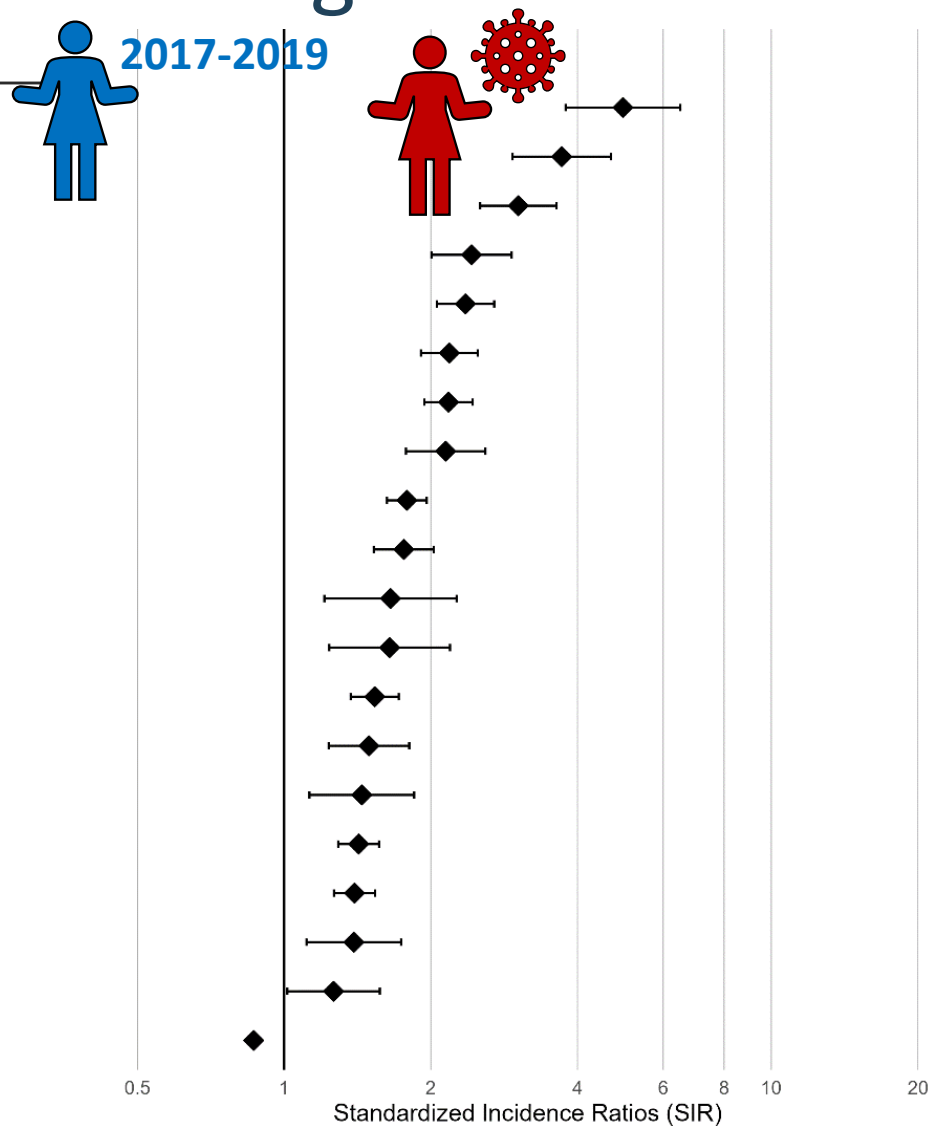
Standardized Incidence Ratios Forest Plot with Meta Analysis of AESIs

Source	SIR (95% CI)
Pulmonary Embolism	11.77 (10.08 - 13.73)
Disseminated Intravascular Coagulation	8.79 (7.13 - 10.85)
Myocarditis Pericarditis	7.70 (6.61 - 8.98)
Guillain Barre Syndrome	6.79 (5.03 - 9.17)
Encephalomyelitis	5.94 (4.59 - 7.70)
Thrombosis with Thrombocytopenia (TWT)	5.60 (4.74 - 6.62)
Deep Vein Thrombosis (DVT)	5.56 (4.57 - 6.76)
Acute Myocardial Infarction	4.70 (4.07 - 5.43)
Non-hemorrhagic Stroke	4.59 (3.95 - 5.34)
Hemorrhagic Stroke	3.86 (3.26 - 4.57)
Immune Thrombocytopenia (ITP)	3.37 (2.96 - 3.82)
Transverse Myelitis	2.53 (2.01 - 3.17)
Anaphylaxis	1.93 (1.56 - 2.40)
Bells Palsy	1.84 (1.60 - 2.12)
Appendicitis	1.72 (1.47 - 2.02)
Narcolepsy	1.32 (1.05 - 1.66)



Standardized Incidence Ratios Forest Plot with Meta Analysis of Negative Controls

Source	SIR (95% CI)
Open wound of buttock	4.96 (3.78 - 6.51)
Poisoning by bee sting	3.71 (2.94 - 4.68)
Ankle ulcer	3.03 (2.52 - 3.62)
Animal bite wound	2.42 (2.01 - 2.93)
Biliary calculus	2.36 (2.06 - 2.70)
Leukemia	2.18 (1.91 - 2.50)
Alcoholic liver damage	2.17 (1.94 - 2.44)
Burn of lower leg	2.15 (1.78 - 2.59)
Primary malignant neoplasm of pancreas	1.79 (1.63 - 1.96)
Hyperplasia of prostate	1.76 (1.53 - 2.03)
Endometriosis of uterus	1.65 (1.21 - 2.26)
Intestinal parasitism	1.65 (1.24 - 2.19)
Contusion of toe	1.53 (1.37 - 1.72)
Tailor's bunion	1.49 (1.23 - 1.81)
Benign neoplasm of ovary	1.44 (1.13 - 1.85)
Cervical spine ankylosis	1.42 (1.29 - 1.57)
Cannabis abuse	1.39 (1.27 - 1.54)
Prosthetic joint loosening	1.39 (1.11 - 1.74)
Burn of digit of hand	1.26 (1.02 - 1.57)
Sprain of spinal ligament	0.87 (0.84 - 0.89)



Conclusions

- To our knowledge this is the largest study to date on the descriptive epidemiology of AESIs among the COVID-19 population.
- **Considerable heterogeneity in the IR** among the COVID-19 cohort by geographic areas and databases
- **Considerable variability with age and some with sex groups** emphasizing the need for age and sex stratification when assessing risks and benefits of COVID 19 vaccines
- **Thrombotic events** such as AMI, strokes, DVT, and pulmonary embolism were more frequent compared to other AESIs and **were "uncommon" to "common" in older COVID-19 subjects**.
- In most databases, the **risk of these thrombotic events was higher among COVID-19 subjects when compared to the 'pre-pandemic background population'** of the data sources with a pooled standardized incidence ratio above.

Conclusion

- The results help put the risk of the AESIs post vaccination versus post COVID-19 infection into perspective.

60 Co-Authors

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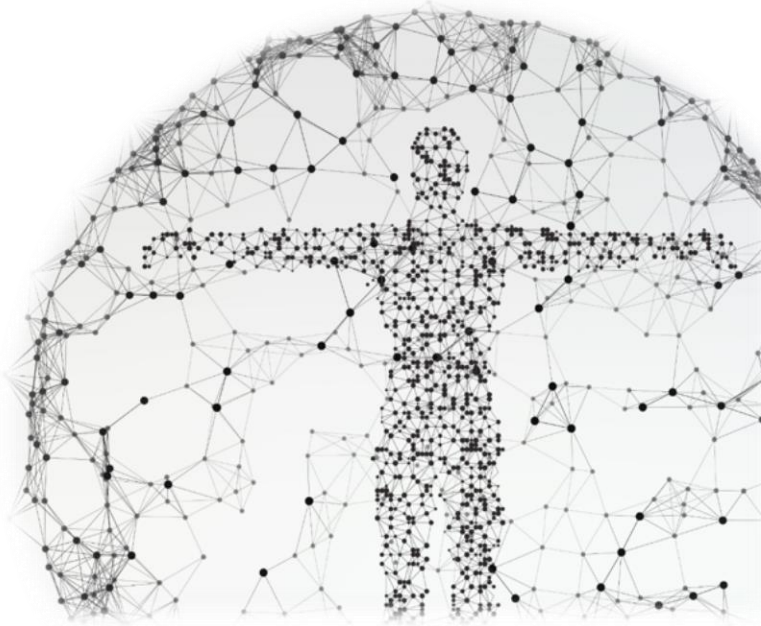
Coordination Centre

Introduction of the DARWIN EU® Coordination Centre

Prof. dr. ir. Peter R. Rijnbeek
Executive Director

OHDSI Europe Symposium June 24th 2022



Disclosure

This presentation represents the views of the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the European Medicines Agency or the European Medicines Regulatory Network.

Problem definition

The European Union (EU) has a rich and diverse healthcare data landscape. However, this diversity brings challenges in terms of a common data structure, terminology, and governance.

There is limit access to data, and the processes for accessing and analysing data for regulatory purposes are slow and complex.

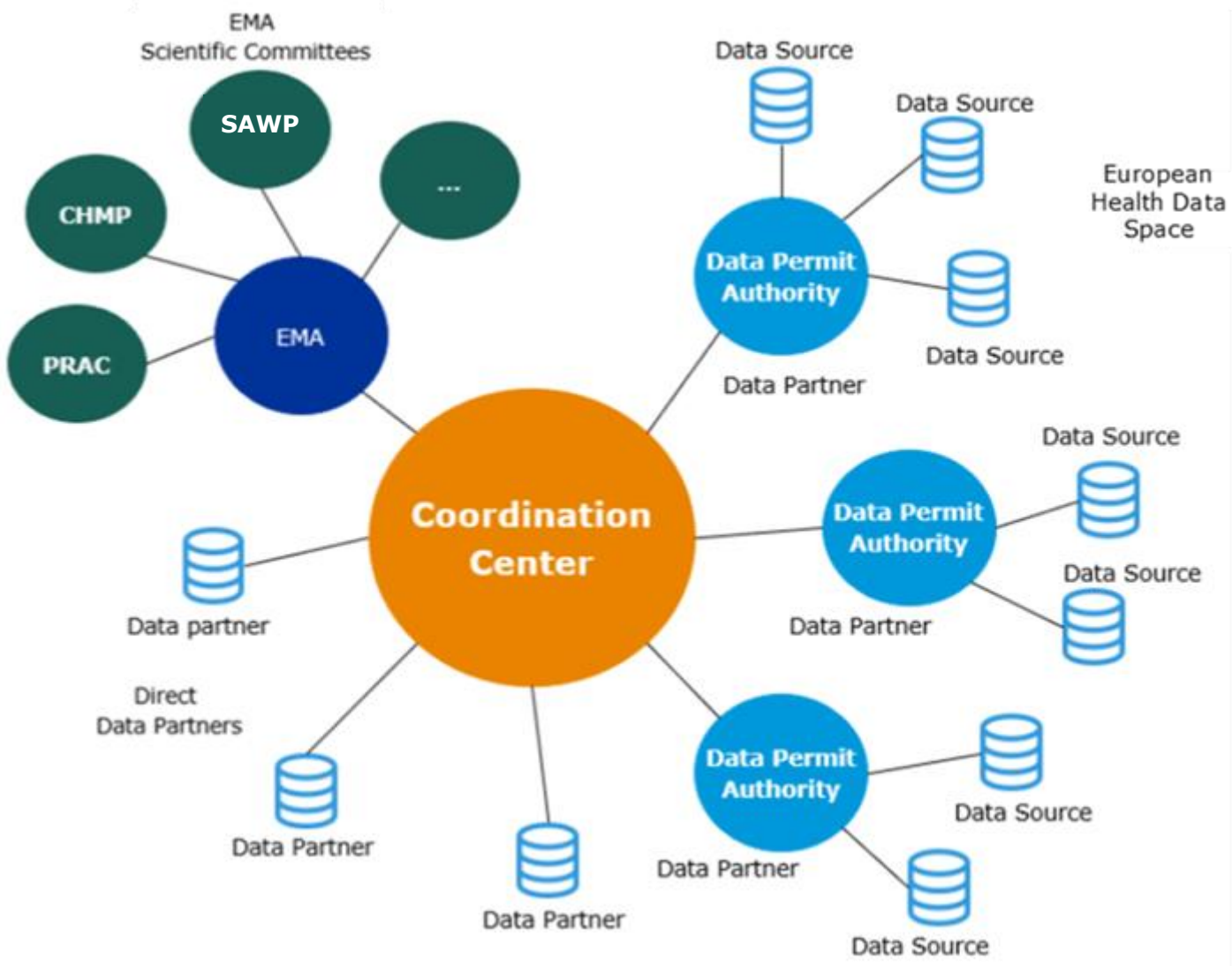
DARWIN EU® Vision

To establish and maintain a framework supporting better decisionmaking throughout the lifecycle of medicinal products with timely, valid and reliable evidence from real world healthcare.

Objectives:

1) To establish and maintain a continually enlarging network of accessible observational data sources
2) To execute all steps of high quality non-interventional studies with the network
3) To make the study results available to the EU Regulatory network to support decision-making

DARWIN EU® is a federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**



FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of the OMOP CDM** to perform studies in a timely manner and increase consistency of results

EMA’s Role

EMA will be a principal user of DARWIN EU, by requesting studies to support its **scientific evaluations** and regulatory decision-making.

EMA will also play a central role in developing, launching and maintaining DARWIN EU, by:

- providing strategic direction and setting standards;
- overseeing the coordination centre and monitoring its performance;
- ensuring close links to European Commission policy initiatives, particularly the EHDS, and delivering pilots;
- reporting to EMA's Management Board, the HMA and European Commission.

A service provider will act as the **DARWIN EU Coordination Centre** and be responsible for setting up the network and managing its day-to-day operations.

What analyses and studies will DARWIN EU® deliver?

Category of observational analyses and studies	Description
Off-the-shelf studies	Studies for which a generic protocol is adapted to a research question
Complex Studies	Studies requiring development or customisation of specific study designs, protocols, phenotypes, or Statistical Analysis Plans (SAPs)
Routine repeated analyses	Routine analyses based on Off-The-Shelf or Complex Studies (see above), repeated periodically (e.g. yearly)
Very Complex Studies	Studies which cannot rely only on electronic health care databases, or which would require complex and/or novel methodological work

Budget and expected number of studies

PHASE I Establishment – 1st year → PHASE II Establishment – 2nd year → PHASE III Operation – 1st year → Operation 2nd year → Operation 3rd year

	Year 1	Year 2	Year 3	Year 4	Year 5
Phases/Options	Phase I	Phase II	Phase III	Option 1	Option2
Estimated budget (in million EURO)	**4M**	**8M**	**8M**	**16M**	**16M**
Routine repeated Analysis	At least 1 study	At least 6 studies	At least 30 studies	At least 60 studies	At least 60 studies
Off-the-shelf Study	At least 2 studies	At least 6 studies	At least 30 studies	At least 60 studies	At least 60 studies
Complex Study	1	4	At least 12 studies	At least 24 studies	At least 24 studies
Very complex Study	0	0	0	At least 1 study	At least 1 study

Setting up the DARWIN EU® Coordination Centre

DARWIN EU® Coordination Centre

Executive Director
Prof. Peter Rijnbeek
Head of the Department of Medical Informatics
Erasmus MC

Deputy Director
Prof. Daniel Prieto Alhambra
Erasmus MC, Oxford University

Deputy Director
Associate Prof. Katia Verhamme
Erasmus MC

Contractor

Erasmus MC
Universitair Medisch Centrum Rotterdam

Sub-contractors

UNIVERSITY OF OXFORD

SYNAPSE
RESEARCH MANAGEMENT PARTNERS

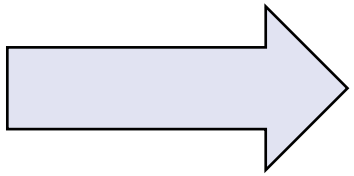
IQVIA

The Hyve

ODYSSEUS
DATA SERVICES INC

DARWIN EU® Implementing a paradigm shift

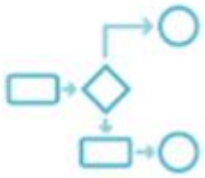
- A highly needed paradigm shift for the fast delivery of reliable evidence for regulatory decision-making on the utilisation, safety and effectiveness of medicinal products throughout their lifecycle
- A long-term investment needed to significantly scale up the number of studies on more databases and improve public health.



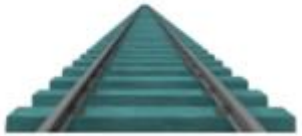
Not possible by simply scaling up the traditional approaches.

What is needed to facilitate observational studies at scale?

Data interoperability



Standardised analytics

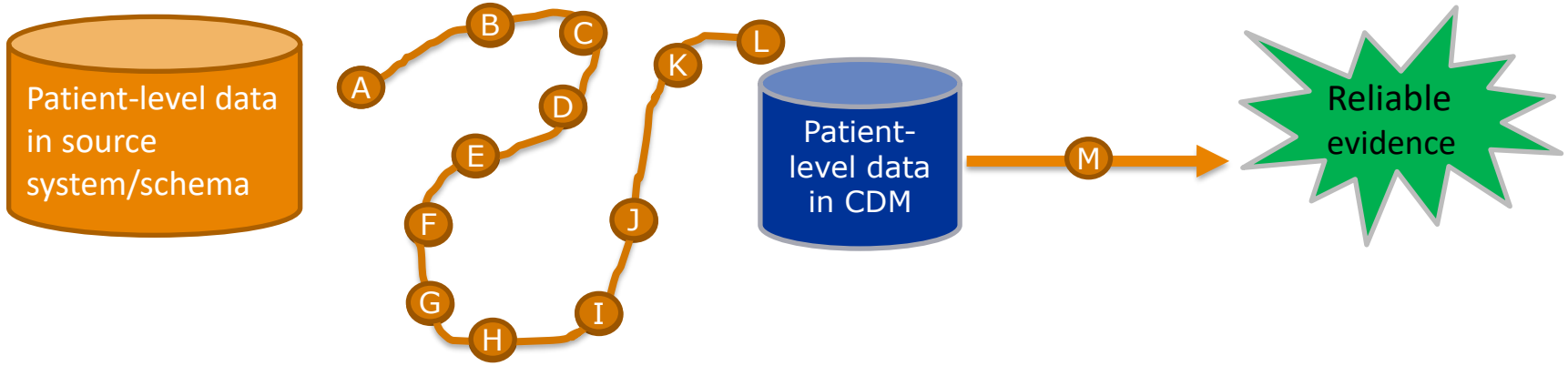


Technical Infrastructure

Data network

Generating Reliable Evidence using the OMOP Common Data Model

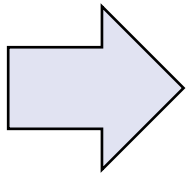
We need to make studies repeatable, reproducible, replicable, generalisable, and robust



A Common Data Model will enable standardised analytics to generate reliable evidence.

Standardising the analytics

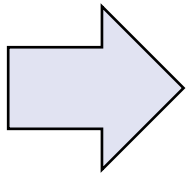
- A catalogue of open source standardised analytics is needed to support ”all” regulatory decision-making on the utilisation, safety and effectiveness of medicinal products



Will require alignment on the priority and choice of the analytical methods, and the standardised output!

Standardising the analytics

- A catalogue of open source standardised analytics is needed to support ”all” regulatory decision-making on the utilisation, safety and effectiveness of medicinal products



Will require alignment on the priority and choice of the analytical methods, and the standardised output!

- Development will be driven by initial studies taking different complexity levels into account.
- The standardised analytics will be based on available tools and methods developed in the OHDSI community.

Creating a strong technical infrastructure

Required components:

- Collaboration Space for CC and Study Teams
- Analytics Platform
- Study Execution Platform
- Training Platform
- Service Desk
- Source Control Repository
- DARWIN EU Website
- …

Operating a high-quality Data Network

- Selection of data partners

  1) Prioritisation of already converted data sources
  2) Potentially mapping highly valued data sources

- All data sources will go through an onboarding process approved by EMA including quality control steps

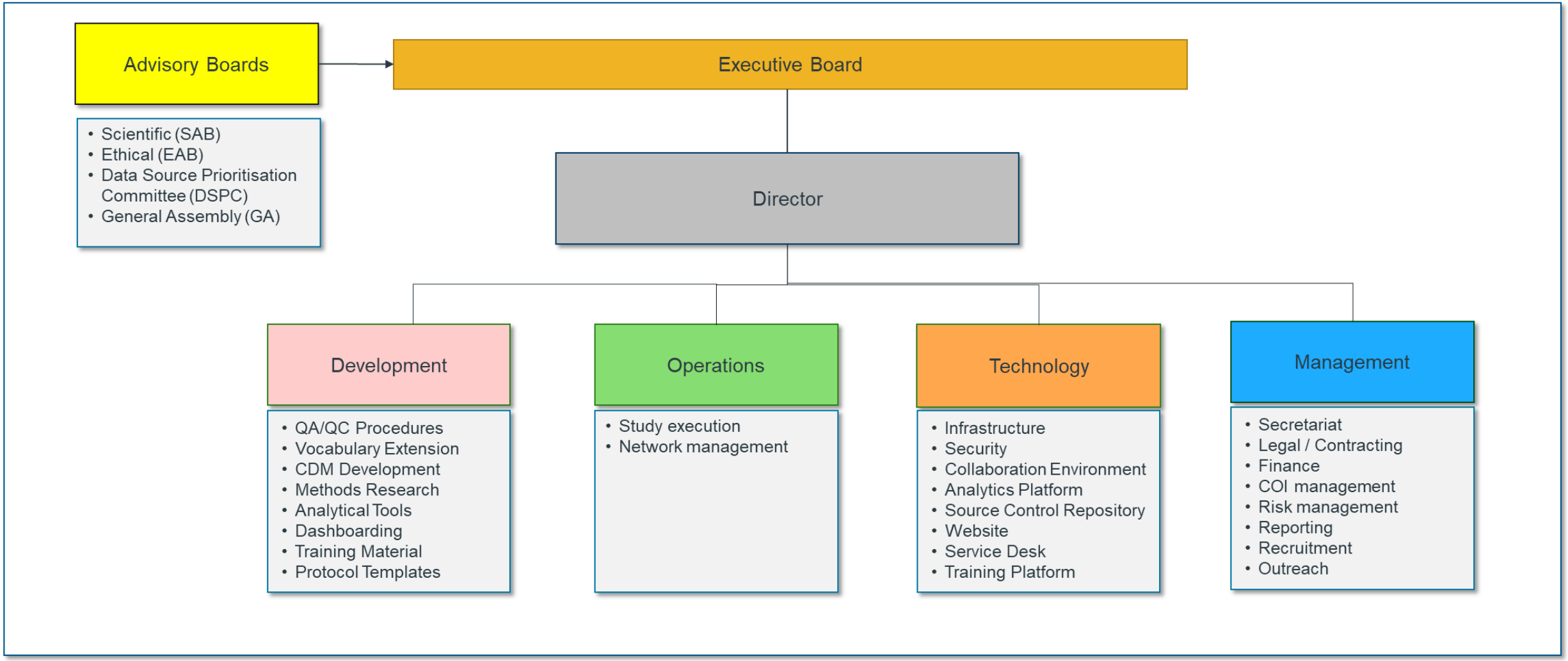
The data network will contain 40 data sources by year 4 (10 per year)

Which data sources will DARWIN EU® use?

Data sources will be onboarded over time taking into account the following criteria:

- Data sources collecting health data routinely and representative of the different types of real-world data in terms of data elements, setting (primary & secondary care), population, origin (e.g. electronic health care records, claims)
- Data sources which collectively provide a broad geographical cover
- Data sources containing patient-level data with a unique patient identifier linking all records relating to a given patient
- Medicines prescribed or dispensed identifiable with quantities (e.g. doses, package size) and dates allowing to calculate cumulative doses and duration of use and linked to individual but unidentifiable patients
- Clinical events formally coded, with accurate dates and linked to individual but unidentifiable patients
- Data already converted or planned to be converted into the OMOP common data model

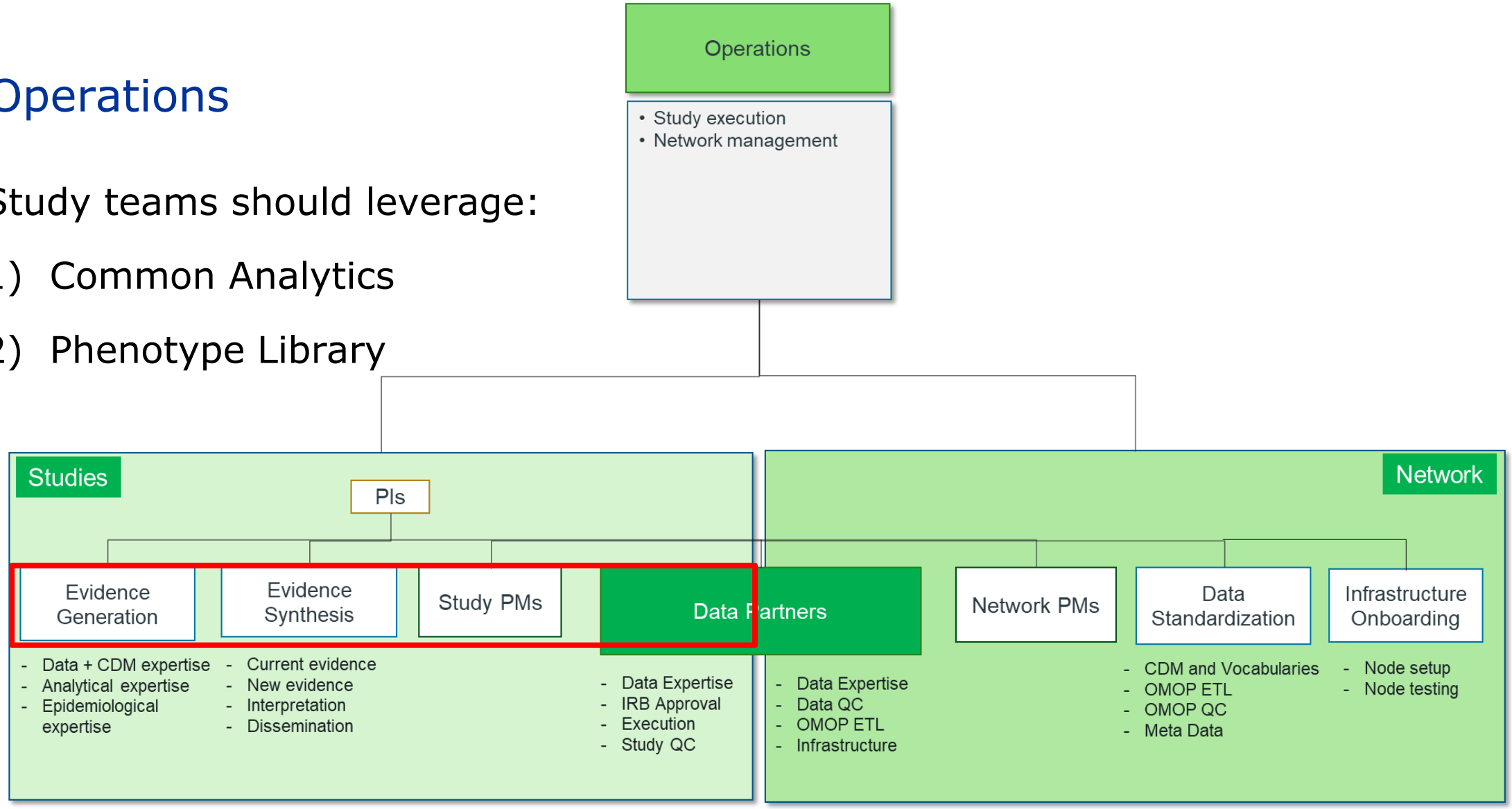
Establishment and Evolution of the Coordination Centre



Operations

Study teams should leverage:

1) Common Analytics
2) Phenotype Library



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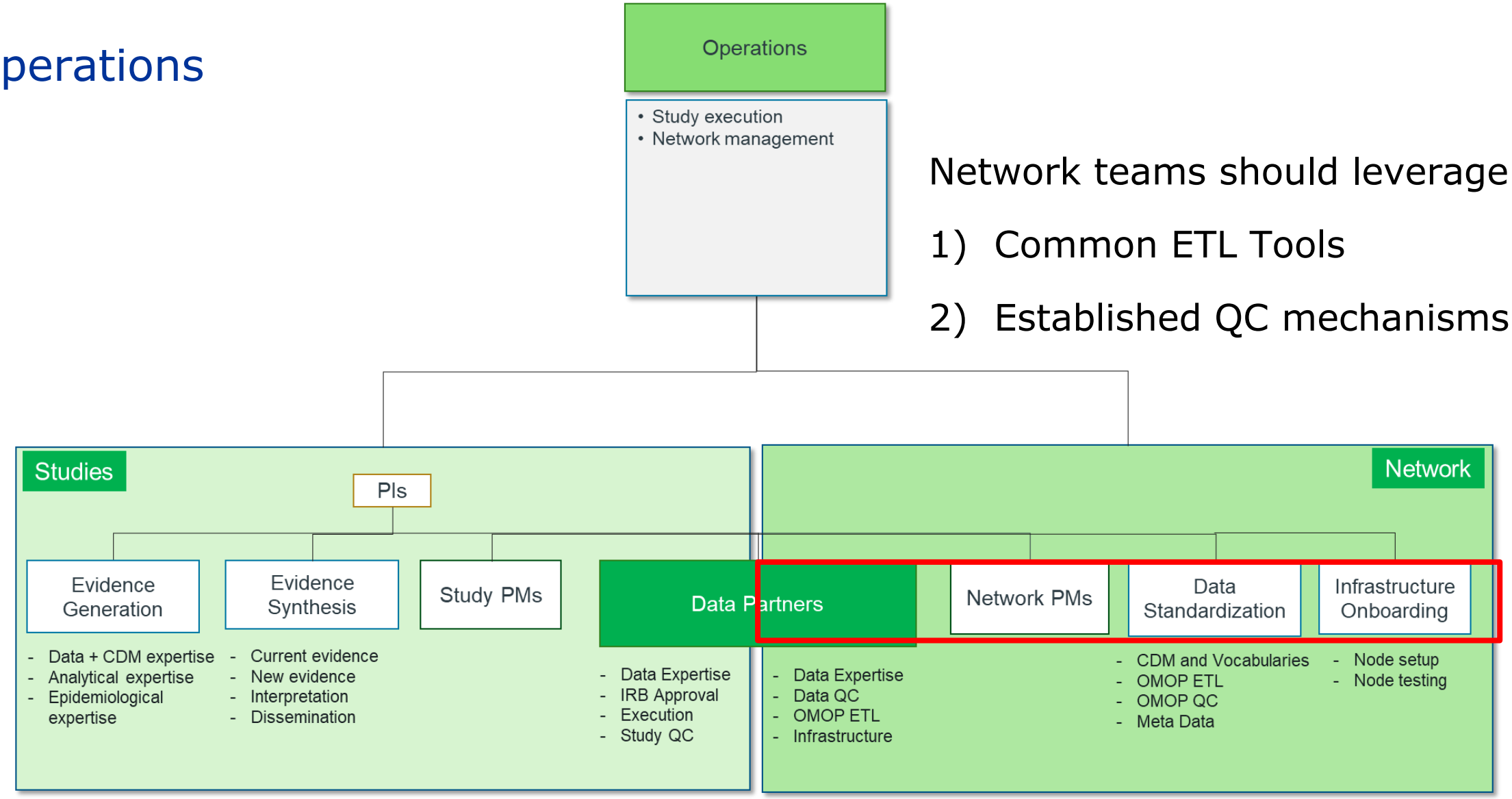

Network teams should leverage:

1) Common ETL Tools

2) Established QC mechanisms

Implementation roadmap

Phase I - 2022

- Start running pilot studies to support EMA committees – **first benefits delivered**
  - Coordination Centre set-up
  - Data Protection Impact Assessment
  - Start recruiting and onboarding data partners
  - Pilot with the EHDS model and existing Data Permit Authorities
- Consultation of stakeholders

Phase II - 2023

- Support the majority of Committees in their decision-making with reliable RWE by 2023

Phase III - 2024

Upscale delivery and capacity to routinely support the scientific evaluation work of EMA's scientific committees and NCAs by delivering studies and maintaining data sources.

Operation - 2025/2026

- DARWIN EU® to be fully operational and yearly evolves to meet the needs from the EU Regulatory Network
- **Integration with the EHDS**

DARWIN EU® - Coordination Centre considerable progress made

- **Formation** of the coordination centre: governance team, technology operations team, governance & boards
- **Project management** (e.g. project plan, risks management, reporting, Conflict of Interest management process)

- **On-Boarding of data sources**:
  - Process for data partner selection
  - On-boarding specifications, data use agreement drafts
- **Development of study templates**:
  - Feasibility assessment form
  - study outline/protocol/report, agreement for Study Participation (under review)
- **Catalogue of standardized analytics**:
  - Agreement of study type definition
  - Implementation initiated

More Information

[Data Analysis and Real World Interrogation Network (DARWIN EU) | European Medicines Agency (europa.eu)]

Coordination Centre website – available next month

- For questions to the Coordination Centre, please contact: enquiries@darwin-eu.org

For regular updates on DARWIN EU® Subscribe to the Big Data Highlights newsletter by sending an email to: bigdata@ema.europa.eu

01 Issue 1 February 2022

HMA Heads of Medicines Agencies

EMA EUROPEAN MEDICINES AGENCY

BIG DATA

HIGHLIGHTS

Quarterly update on implementation activities of the HMA-EMA Big Data Steering Group workplan

Editorial

Peter Arlett

Co-chair of Big Data Steering Group/ Head of Data Analytics and Methods Task Force, EMA

Jesper Kjær

Co-chair of Big Data Steering Group/ Director of Data Analytics Centre, DKMA

INSIDE THIS ISSUE

Editorial 1
Featured topics 2
BDSG Annual report 3
Stakeholder engagement 4

Welcome to the first edition of the newsletter on Big Data which reports on the implementation of the HMA-EMA Big Data Steering Group workplan 2021-2023 and the data and digital pillar of the Network Strategy 2025.

The BDSG was established in May 2020 with the mandate to take forward and advise on implementation of the priority recommendations set out in the Big Data Task Force final report (phase two). The vision, set out by the Big Data Taskforce that guides delivery of the workplan is that:

> *by delivering a regulatory system able to integrate Big Data into its assessment and decision making, we can support the development of innovative treatments more quickly and optimise the safe and effective use of medicines.*
>
> **Big Data Task Force Final Report, Dec 2019**

Already in 2021, we have seen an impressive array of activities and outputs that support transformation to data-driven medicines regulation. These include the finalisation of the network's data standardisation strategy and a series of technical workshops covering standardisation, real-world data, artificial intelligence, veterinary data and real-world evidence. More details on the 2021 deliverables are included later in this newsletter.

Moving forward, we are excited to be able to share with you more regular updates on big data and the implementation of the BDSG workplan via this newsletter. We look forward to collaborating and leveraging the work of stakeholders to increase the utility of big data in medicines regulation.

The Big Data Steering Group welcomes your feedback and questions you may have by email at bigdata@ema.europa.eu .

We hope you find the Big Data Highlights informative!

Reaction Panel with Key Stakeholders

Dani Prieto-Alhambra, MD, PhD

Professor of Pharmaco- and Device Epidemiology University of Oxford

Professor of Real-World Evidence and Methods Research, Erasmus MC

REACTION PANEL

- **Chair**: Dani Prieto-Alhambra, University of Oxford and EMC Rotterdam

- **Panellists**:
  - Catherine Cohet, European Medicines Agency
  - Filip Maljkovic, Clinerion Serbia Rep
  - Daniel Morales, Dundee University and HIC
  - Patrick Ryan, Janssen

Closing Remarks

Peter R. Rijnbeek
Professor of Medical Informatics
Department of Medical Informatics
Erasmus MC, The Netherlands

A great journey ahead!

- Further growth of the Data Network
- Number of National Nodes will grow
- Many research studies on more data sources
- Many publications on methods
- Further expansion of training curriculum driven by the European Health Data and Evidence Network (EHDEN)
- And much more..

Join the Community

Join Our Workgroup Efforts!

Form To Join Workgroups In MSTeams | **Weekly Workgroup Meeting Schedule**

Get To Know The OHDSI Workgroups

Asia-Pacific (APAC)
Current Participants: 278
Lead: Mui Van Zandt
2022 OKRs

ATLAS/WebAPI
Current Participants: 192
Lead: Anthony Sena
2022 OKRs

Clinical Trials
Current Participants: 229
Leads: Mike Hamidi, Lin Zhen
2022 OKRs

Common Data Model
Current Participants: 520
Lead: Clair Blacketer
2022 OKRs

Data Quality Dashboard Development
Current Participants: 218
Lead: Clair Blacketer
2022 OKRs

Early-Stage Researchers
Current Participants: 178
Leads: Faaizah Arshad, Ross Williams
2022 OKRs

Education
Current Participants: 97
Lead: Nigel Hughes
2022 OKRs

Eye Care & Vision Research
Current Participants: 19
Leads: Sally Baxter, Kerry Goetz
2022 OKRs

Upcoming OHDSI Community Calls

Date	Topic
June 14	OHDSI Scholarship (Publications)
June 21	10-Minute Tutorials
June 28	European Symposium Recap
July 5	NO MEETING
July 12	New Adopter Introductions and Q&A
July 19	Workgroup Updates
July 26	CDM Update Process

@OHDSI www.ohdsi.org #JoinTheJourney ohdsi

EHDEN Academy
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

OHDSI Global Symposium
October 14-16 Bethesda North Marriot Hotel & Conference Center

Workshop Saturday

Workshop “Designing and Implementing a network characterization study

Lead: Patrick Ryan, Janssen Research and Development

Room: Collegezaal 1, Educational Centre Erasmus MC.

Time: 8:30 – 16:00

Bring your name badge

Workgroup Meeting Sunday

Sunday 26th	Parallel Workgroup Meetings Educational Centre Erasmus MC.
Time	**Description**
09.30 – 10.00	Coffee
10:00 – 12:30	During this day several meetings will be organized by OHDSI Working Groups and opportunities to meet experts Morning sessions: - Educational WG (Nigel Hughes) - Location: OWR 23 - HADES WG (Martijn Schuemie) - Location: OWR 35 - Oncology WG (Asieh Golozar) - Location: OWR 36 - Vocabulary WG (Michael Kallfelz) - Location: OWR 31
12:30 – 13:30	Lunch
13:30 – 16:00	Afternoon sessions: - Patient Level Prediction WG (Ross Williams, Jenna Reps) - Location: OWR 35 - OMOP-FHIR WG (Christian Reich) - Location: OWR 31 - ETL/CDM WG (Erica Voss, Maxim Moinat) - Location: OWR 23
16:00 – 17:30	Closure Drink


The 3rd OHDSI APAC Symposium
Taipei Taiwan (onsite and virtual)
Nov 12-13, 2022
OHDSI
TAIWAN

A new addition to the OHDSI Europe Goodieslist

EUROPEAN OHDSI SYMPOSIUM

EUROPE

June 24th 2022 Rotterdam

Organised by:

Erasmus MC
University Medical Center Rotterdam

Health Data Science

Group Photo

But first something else…

How to close this symposium..

2018

2019

Join the OHDSI Band!









EUROPEAN OHDSI SYMPOSIUM

EUROPE

June 24th 2022 Rotterdam

We look forward to seeing you at the next OHDSI Symposium

Organised by:

Erasmus MC
University Medical Center Rotterdam

Health Data Science