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ADVANCE solutions to generating evidence from heterogeneous health data

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on behalf of WP5 ADVANCE consortium

WHAT EVIDENCE SHOULD THE SYSTEM BE ABLE TO GENERATE?

Background rates

Vaccine coverage /exposures

Benefits of vaccination (effectiveness/impact)

Safety information

Near real time benefit-risk monitoring

From post-marketing (real world data) data residing with different stakeholders across Europe

ADVANCE DATA SOURCES N=19 IN CONSORTIUM

Type	Names	Countries	Outcomes
Disease surveillance	pediatric surveillance, GP surveillance, lab surveillance, OSIRIS	Belgium, Netherlands	Reported cases
Trial cohorts	HPV trial cohort Tampere	Finland	linkage to in-outpatient registries
General Practice	RCGP, THIN, BIFAP, SIDIAP, ARIANNA, IPCI, PEDIANET	UK, Spain, Italy, Netherlands	outpatient and reported inpatient Dx
Claims record linkage	Aarhus, SSI, ASL Cremona, ARS, Sweden	Denmark, Italy, Sweden	hospital discharge/ER

together more than 40 million persons source population

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How did we work together and overcome differences in data structure and the fact that data are located in different places?

Simple Common Data Model
Codemapper for semantic harmonization (see as tool during lunch)
Common analytics

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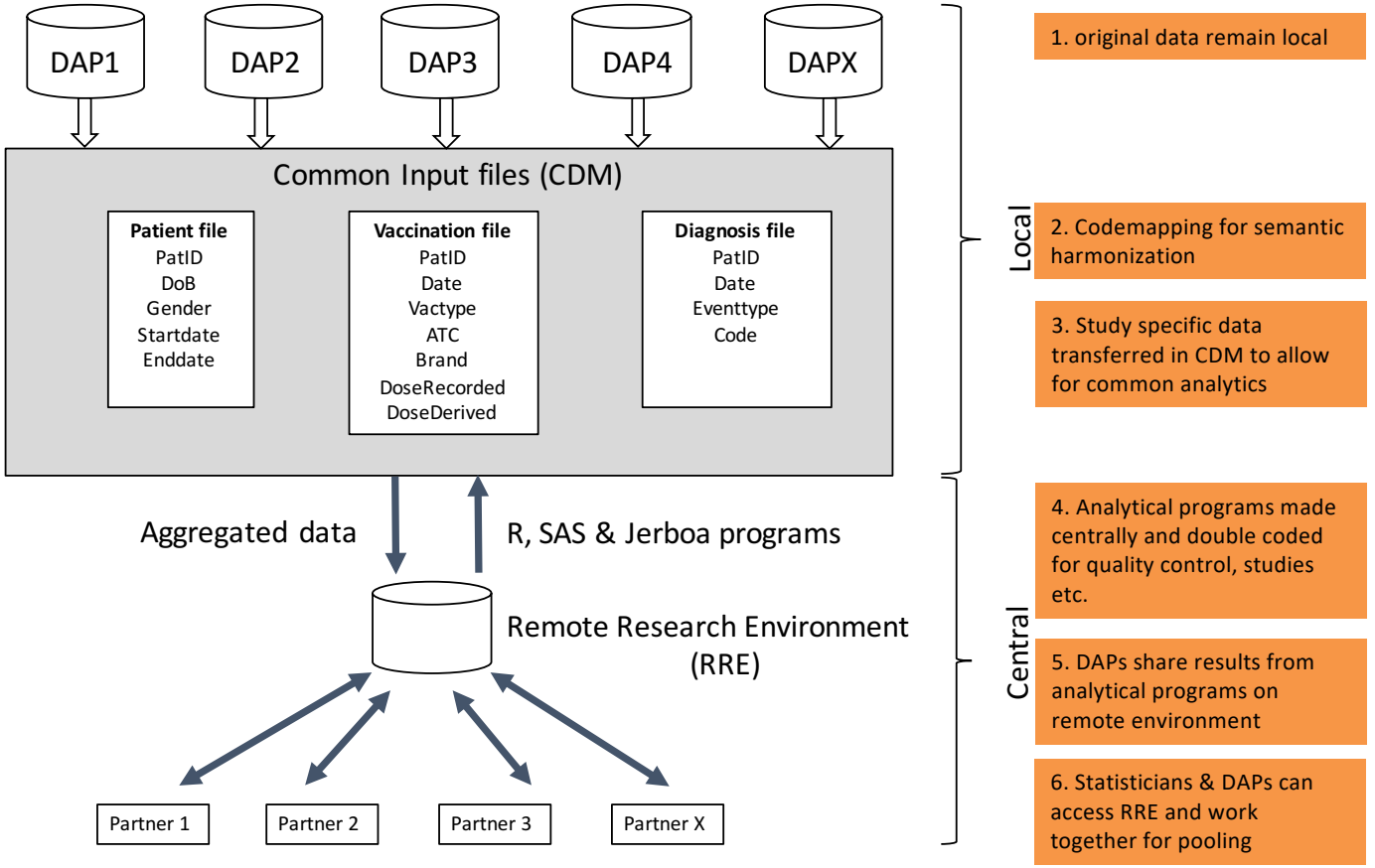
How to work together and overcome differences in structure?



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Are available health care data good enough for studies?

Extensive Fingerprinting program (checks on population, vaccine and event file in CDM)
Benchmarking (vaccine coverage estimates and disease incidence rates) between databases and with external benchmarks

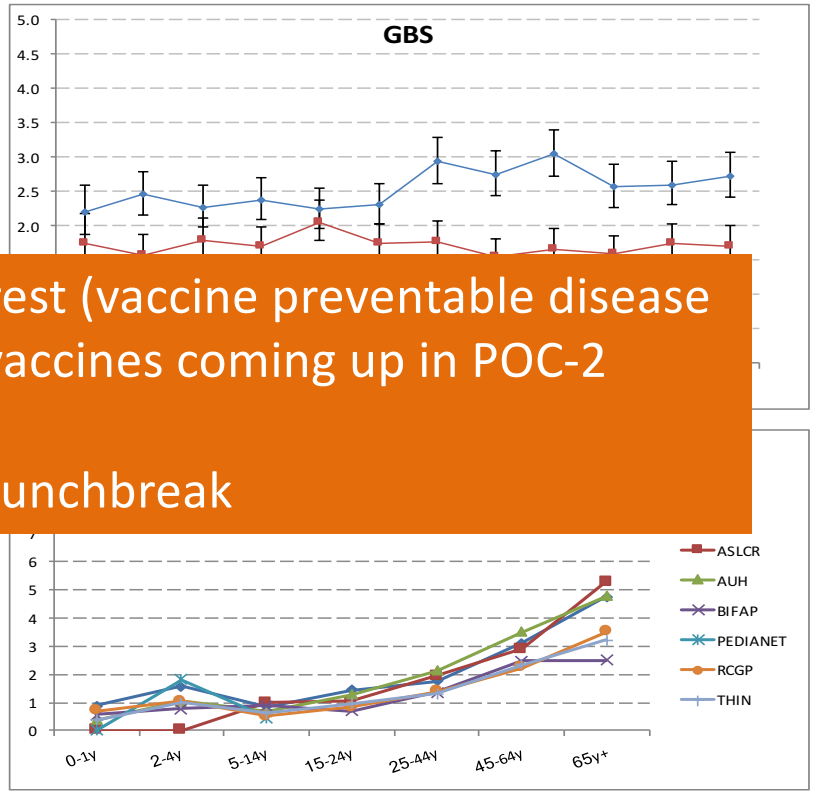
see Fingerprint tool during lunch break

FINGERPRINT EXAMPLES TO ASSESS WHETHER DATA ARE FIT FOR PURPOSE

Vaccination fingerprint

HPV coverage dose 1 by age in girls

Event fingerprint



Systematically conducted for 25 events of interest (vaccine preventable disease and safety events, and 4 vaccines, other vaccines coming up in POC-2

see fingerprint booth at lunchbreak

courtesy: Braeye, Willame

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How did we test the system?

Six protocol based proof of concept studies with databases considered ‘fit for purpose’

Assessing ability to generate robust evidence with the system: known outcome
Time it took

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PROOF OF CONCEPT STUDIES

POC 1: Retrospective studies comparing acellular pertussis vaccine against whole cell in children 0-5 years

POC 1.2: Using protocols & analytics from POC-1, conduct prospective near real time monitoring of coverage, benefits and risks for acellular pertussis vaccine in children 0-5 years of age

POC-2: Assess exposure and coverage to routine vaccines, including brands

Study	POC-1 (Retrospective)	POC1.2 (Near real time)	POC-2 (Coverage)
Coverage	7 databases: Denmark (SSI, AUH), Italy (Pedianet), UK (THIN, RCGP-RSC), Spain (SIDIAP, BIFAP) Time Protocol 6 months approval Running: 6 months Reporting: 6 months	3 databases (Val Padana, Denmark, RCGP-RSC) Time protocol: 1 month approval Running: 3 months (prospective) Reporting: 6 months	10 databases: Denmark (SSI, AUH), Italy (Pedianet, ARS, Val Padana), UK (THIN, RCGP-RSC), Spain (SIDIAP, BIFAP), NL(RIVM) Time Protocol: 1 month approval Running: 2 months Reporting: ?
Risk			
Benefit			
B/R assessment			

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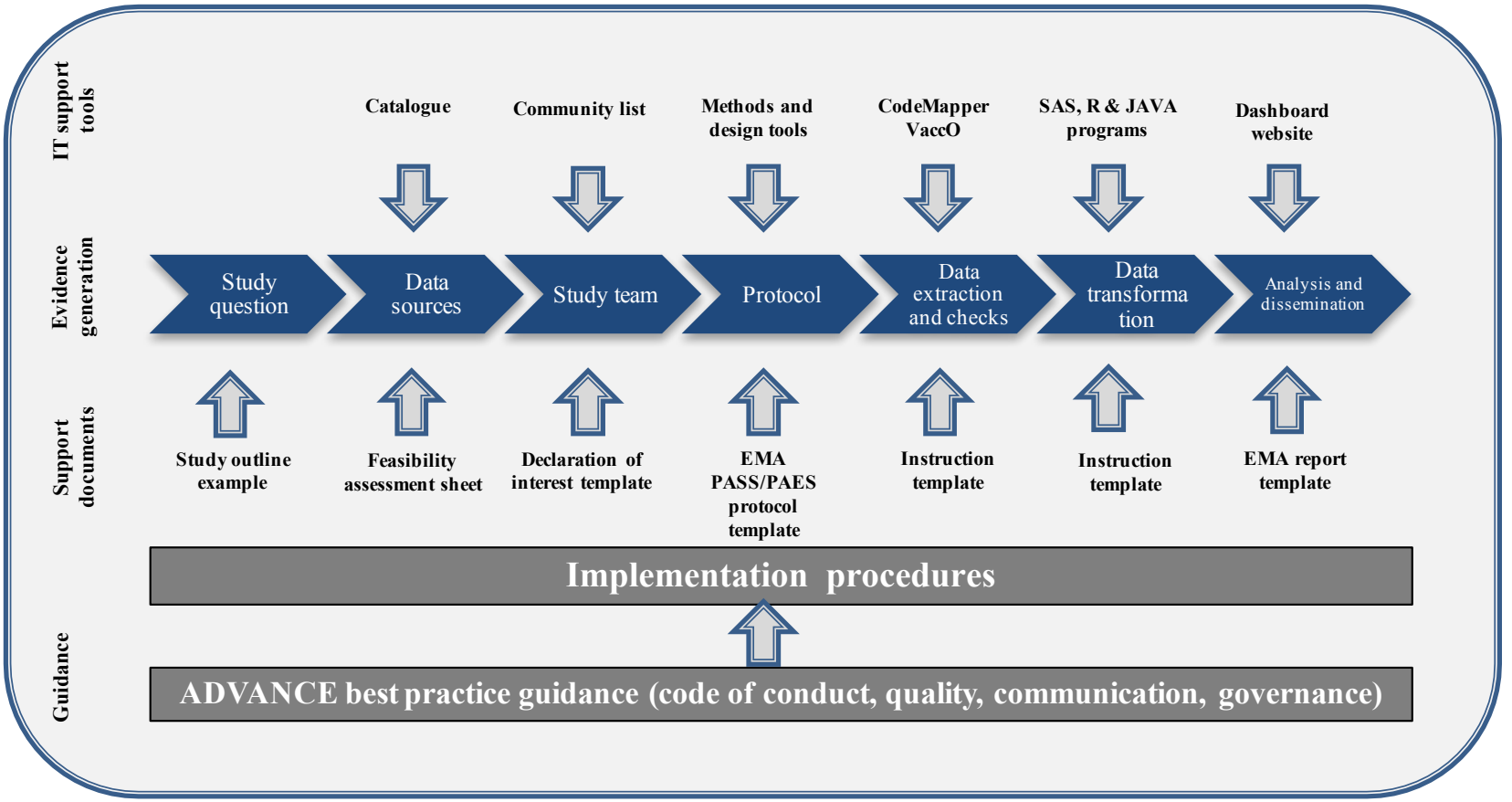
How to create timelines: READINESS TO ACT People, Data, analytics



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How to create timelines: Readiness To Act
People, Data, analytics: PROCESS MAP

Readiness to act	Study process						
Pre-study	Protocol and Statistical analysis plan (SAP)				Data extraction	Data transformation	Analysis & reporting
Identification of potential databases in catalogue	Planning	Study team	Protocol	Statistical analysis plan	Send instructions to DAPs	Write data transformation programs	Write final analysis and pooling programs
Collection of experience from DAPs for events / vaccines	Study question	Identification of partners and roles	Write study protocol	Write statistical analysis plan and dummy tables	Data extraction / refresh	Test programs and quality control	Quality control program
Code mapping	Feasibility assessment	Collect CVs and declaration of interest	Review of study protocol	Create instructions and CDM content for DAPs	Fingerprint and data quality checks	Run data transformation programs	Review of analyses
Extraction of data and components	Study outline	Agree on study team	Update study protocol	Approval SAP	Approve study data extraction	Transfer output to RRE	Draft report
Quality control and sharing of output	Identification of potential databases	Select governance model	Approval study protocol			Review and approve output	Review of report
Benchmark of data	Approval of study outline	Sign contract	Register study protocol EU PAS				Finalisation of report
Archival of codes and algorithms	DAPs: database access providers; CDM: common data model						Upload report to EU PAS

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People readiness, Data readiness and Analytics readiness

Innovative Medicines Initiative efpia