



# THE EHR4CR PILOTS: A REAL SUCCESS

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# Validated solutions

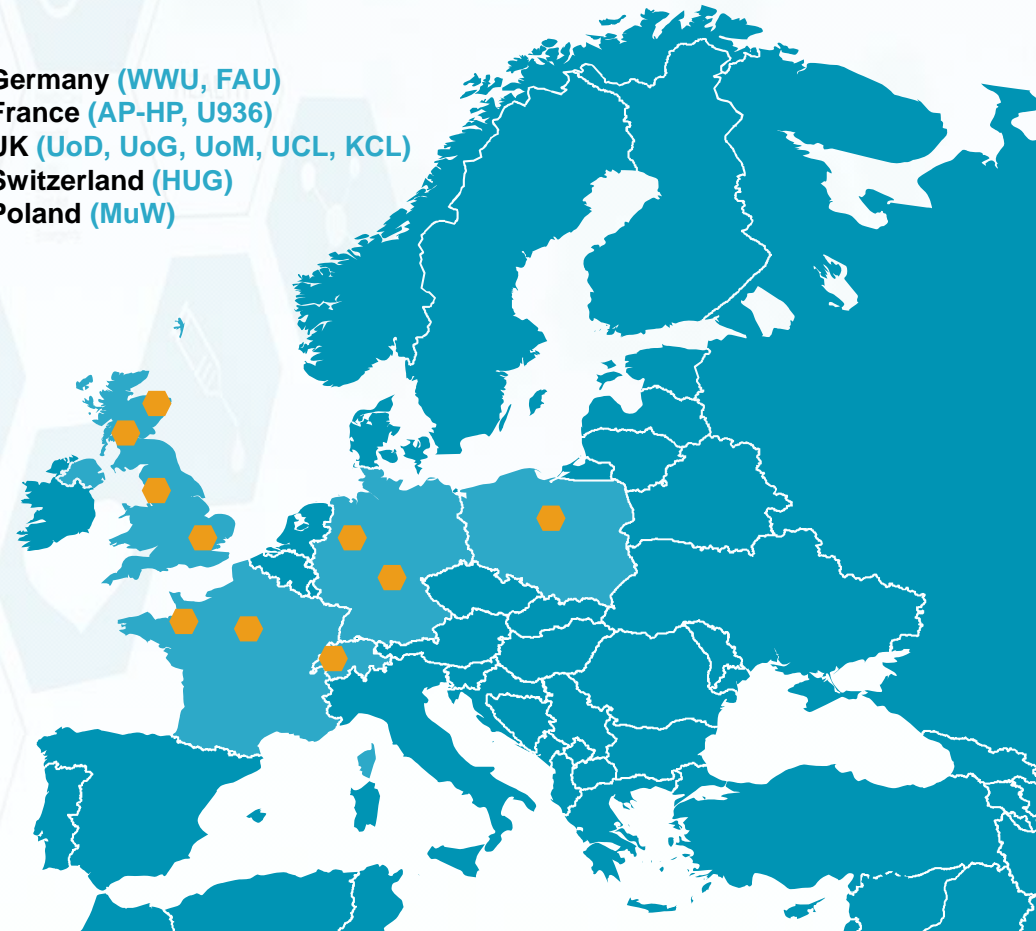
- Developed pilots to validate the solutions:
  - For different **scenarios** (e.g. protocol feasibility)
  - Across different **therapeutic areas** (oncology, inflammatory diseases, neuroscience, diabetes, cardiovascular diseases, respiratory diseases)
  - Across **several countries** (under different legal frameworks)



# Protocol Feasibility Service pilot

- Tested viability and performance of EHR4CR platform to support protocol feasibility service
  - **11** major hospitals in **five** countries
  - EHR4CR-compliant data warehouses were established at all pilot sites
  - Large set of eligibility criteria from EFPIA trials analysed to identify commonly used data elements (**75 EHR data elements**)
  - De-identified data from **>five million patients** was loaded for these elements into local EHR4CR-compliant data warehouses as far as available at the sites
  - **12 clinical studies** evaluated, technical testing of four clinical studies

- **Germany** (WWU, FAU)
- **France** (AP-HP, U936)
- **UK** (UoD, UoG, UoM, UCL, KCL)
- **Switzerland** (HUG)
- **Poland** (MuW)



# User acceptance and functionality testing

- A subset of the previously selected 12 studies were used for two User Acceptance Test pilots
  - October 2012: Initial pilot with four studies, test scripts with 52 steps
  - January 2013: Extended pilot with 10 studies
- User functionality testing
  - October 2013: Three independent testers, validation of patient counts

# End user view of the application: Protocol Feasibility Service query workbench

## Terminology

Browse Search

Expand the terminology to search a concept.  
The draggable elements are colored with blue.

Collapse all

- Clinical finding
- Demographic history finding
- Diagnosis
- Drug or medicament
- Morphologically abnormal structure
- Procedure
- Result, lab.- general
- Substance

Constraints : Age Before now X Before Y Occurrence

Male

AND More or equals to 17 Years Old

AND { Malignant neoplasms of ill-defined, } At Most 3 Month Before { Malignant neoplasm of prostate }

AND Bilateral orchidectomy OR cyproterone OR medroxyprogest...

AND NOT { Cryotherapy } OR Prostatectomy OR Radiation oncology AND/OR } At Most 6 Month Before now

Clear Delete

Clear Delete

Clear Delete

Clear Delete

Add a new criterion

Delete All Save the query Run

Options Query Run Status and Results Query in Eclectic Format

QUERY STATUS: [EXECUTING]

Query was distributed at: unknown

Current statistics: 11 endpoints expected and 3 completed

Expected endpoints: HUG, FAU, WWU, APHP, U936, KCL, UoM, UCL, UNIVDUN, UoG, MUW

Finished endpoints: FAU, UNIVDUN, UoG

[See detailed status...](#)

Cancel See Results

Query : A\_test4

QUERY STATUS: [EXECUTING]

Query was distributed at: unknown

Current statistics: 11 endpoints expected and 4 completed

Expected endpoints: HUG, FAU, WWU, APHP, U936, KCL, UoM, UCL, UNIVDUN, UoG, MUW

Finished endpoints: FAU, WWU, UNIVDUN, UoG

[See detailed status...](#)

Result :

[\(Info: The aggregated result is currently not available due to end point incompatibilities. Click here for details ...\)](#)

[FAU \(0\)](#)

[WWU \(0\)](#)

[0 patients match all criteria](#)

[115 patients match: gender\(\) in \(\[SNOMED Clinical Terms:248153007,"Male"\]\)](#)

Age	Male	Female	Undefined	Total
0 to 9	0	0	0	0
10 to 19	0	0	0	0
20 to 29	1	0	0	1
30 to 39	3	0	0	3
40 to 49	9	0	0	9
50 to 59	13	0	0	13
60 to 69	29	0	0	29
70 to 79	26	0	0	26
80 +	34	0	0	34

[200 patients match: born\(\) at least 17 year before now](#)

[0 patients match: last diagnosis\(\[ICD-10:C61,"Malignant neoplasm of prostate"\]\)](#)

[0 patients match: last diagnosis\(\[ICD-10:C76-C80.9,"Malignant neoplasms of ill-defined, secondary and unspecified sites"\]\) at most 3 month before rule\(3\)](#)

[0 patients match: last procedure\(\[SNOMED Clinical Terms:386634006,"Bilateral orchidectomy"\]\)](#)

[0 patients match: last medication\(\[ATC:G03HA01,"cyproterone"\], \[ATC:L02AB02,"medroxyprogesterone"\]\)](#)

[200 patients match: not last procedure\(\[SNOMED Clinical Terms:26782000,"Cryotherapy"\], \[SNOMED Clinical Terms:90470006,"Prostatectomy"\], \[SNOMED Clinical Terms:108290001,"Radiation oncology AND/OR radiotherapy"\]\) at most 6 month before now](#)

[UNIVDUN \(0\)](#)

[UoG \(0\)](#)

# End user view of the application: Results

# Protocol Feasibility Service pilot outcome

- Conclusion of defined pilot success criteria:
  - Retrieving information from hospital sites: 👍
  - Timely response 👍 but endpoints without data halt query execution
  - User functionality testing: patient counts validated for test dataset: 👍
  - EHR chart review to validate precision of patient counts by EHR4CR platform (currently ongoing)
  - Query modification and re-running of queries: 👍 🗑️
  - Transnational platform across systems and hospitals: 👍

# Succeeded in overcoming key hurdles



## Interoperability

Real clinical data uploaded transnationally, from very complex and diverse IT systems, across 10 trials, covering >five million patients and >446 million data points

- Successful mapping of local terminology to central EHR4CR terminology



## Data security, privacy & ethics

Relevant approvals secured for upload of de-identified data to data warehouses

No patient-level data left the hospital environment

Platform generated patient counts only



## Confidence in data

EHR4CR platform generated results

- Patient counts validated by User Functionality Testing
- Ongoing refinement based on outcomes
- Improved hospital EHR data structures to align with international research standards

Further refinement ongoing based on insights from the pilot



# Identified priority EHR data elements for the Protocol Feasibility Service

- Consented Protocol Feasibility Service Data Inventory (EFPIA members)
  - Subset of EHR data elements prioritised (75 data elements)
    - Organic inventory
    - Data elements readily available in hospitals
- Data inventory published in *Trials*
- Plans to seek standardisation of data elements across variable EHR systems

**Standardised EHR data is a valuable asset for hospital data processing and warehousing**

# Patient Recruitment Service pilot

- **13** clinical studies identified
  - **11** chronic diseases; **four** acute diseases; **eight** diseases located across **multiple EHR4CR sites**
  - Patient recruitment criteria were simplified and mapped between central and local terminology
    - ETL (extract-transformation-load) into local data warehouses is ongoing
- Consented evaluation protocol
  - Currently under review by Institutional Review Boards; dual IRB approval required at each site

- **Germany (WWU, FAU)**
- **France (AP-HP)**
- **UK (UoD, UoG, UoM, KCL)**

**Trial execution & safety adverse event reporting pilot ongoing**

