Trial feasibility assessments in federated hospital Electronic Health Record networks, based on OMOP CDM

An objective of the IMI2 EU-PEARL Consortium

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INTRODUCTION

- Hospital Electronic Health Record (EHR) systems can inform the design of clinical trial protocols and optimize recruitment.
- EU-PEARL aims to assess the potential to use the OHDSI tooling and the OMOP CDM to evaluate protocol feasibility in hospital EHR networks.
- Here, we present results of a trial feasibility study in Neurofibromatosis Type 1 (NF1) with Optical Pathway Glioma (OPG) in the Erasmus MC hospital EHR system, using Atlas.

METHODS

Reusable NF1-OPG phenotype algorithms, two only based on diagnosis codes (D) and two also based on follow-up visits (F) :

D1: NF1 diagnosis & OPG diagnosis

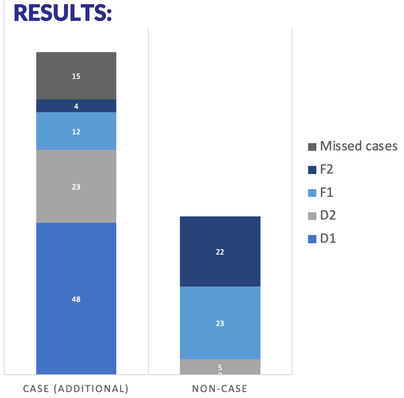
D2: OPG diagnosis

F1: NF1 diagnosis & brain MRI & 4 encounters with an ophthalmologist within 365 days

F2: NF1 diagnosis & brain MRI & 3 encounters with an ophthalmologist within 365 days

- To identify missing cases, selected patients were compared with a list of known OPG patients.
- Patients additionally selected via the Atlas phenotype algorithms were classified as cases or non-cases via clinical chart review.

RESULTS:



Number of cases and non-cases included by each Atlas phenotype algorithm. D1 initially included 48 cases. Using D2, an additional 23 cases were included. With F1 and F2, 12 and 4 cases were identified. Each step also included more non-cases. 15 cases were not included in any of the 4 definitions.

OMOP CDM/ATLAS allows **identifying Neurofibromatosis Type1 patients** with an **Optical Pathway Glioma** in the **Electronic Health Record** database of a **clinical site.**

Leveraging this approach to a **federated site network** provides the potential to identify patients matching **trial eligibility** criteria on **large scale** and to **refine** criteria as appropriate.

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True cases: 104 (61 from a pre-existing list; 43 additional ones from chart review of Atlas cohorts)

Patients selected by phenotype algorithms:

D1: 48; **D2:** 76; **F1:** 62; **F2:** 90

Atlas cohort	N selected in cohort	N cases compared to original list (n=61)	N cases additionally reviewed (n=43)	Sensitivity (original cases only)	PPV (original and reviewed)
D1	48	36	12	59.0% (36/61)	100.0% (48/48)
D2	76	40	31	65.6% (40/61)	93.4% (71/76)
F1	62	29	10	47.5% (29/61)	62.9% (39/62)
F2	90	32	13	52.5% (32/61)	50.0% (45/90)

CONCLUSION

Summary:

- NF1 patients with an OPG could be identified in the EHR database of a clinical site.
- Clinically meaningful variations between phenotype algorithms could be evaluated.

Note:

- For NF1, being a rare condition, a sensitive phenotype algorithm may be preferrable.
- For more common conditions, one may tend to use more specific algorithms.

Next steps:

1. Share the NF1-OPG phenotype algorithms with other sites of the federated EHR network
2. Obtain large-scale aggregate query results, including patient counts and characteristics
3. Overall and for each individual site, evaluate patient counts against expected prevalence
4. Refine phenotype algorithms as appropriate
5. Re-run the query, identify potential patients, and conduct in depth chart review to confirm eligibility to specific study protocol recruitment criteria
6. Evaluate site recruitment potential and study eligibility criteria

➔ **This promising approach will be replicated in 1-2 other diseases, and a general description of the methodology will be made available through EU-PEARL.**

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