Reviewer’s report

Title: Leveraging the EHR4CR Platform to Support Patient Inclusion in Academic Studies: Challenges and Lessons Learned

Version: 0 Date: 17 Oct 2016

Reviewer: Mona Kanaan

Reviewer’s report:

This is an interesting study with the potential of a long term impact on the recruitment of patients to academic studies. The authors describe the automated operationalisation of inclusion/exclusion criteria using "Electronic Health Records" for clinical research.

Listed below are a number of issues that the authors might want to consider.

- Under "Ethics" the authors report that the study did not require ethical approval, however, they do not mention whether they had the permission from patients involved in the listed studies to use their data for research other than the original intended studies. I am assuming here that the data presented in Additional file 3 is based on the participants of the three studies. I think that the authors should have discussed the ethical issues surrounding use of patient data for purposes other than the original studies that they have agreed to be involved in. Also, it would have been useful to highlight how one can operationalise the systems so that such approval is sought and to discuss the triggers where additional approval might/should be sought.

- In the abstract a brief insight into what are non-structured data, normalisation in what sense, what do medical domains and concepts refer to would be helpful.

- It would have been useful to show a scenario of how using the suggested platform would have improved the screening of patients for inclusion in a clinical study.

- To appeal to wider audience the authors should ensure that abbreviations are spelled on first appearance and try to keep these to a minimum. For example, EFPIA, HEGP, i2b2, UKM, DB, PI,...

- Tables 1 and 2 should be introduced within the text.

- Lines 144-155 further information about the "Selected studies" would have been helpful, for example, time frame of the study and target population, where each was conducted HEGP/UKM.

  o Highlight whether aXa is a case-control study. Is it possible that this study was registered under another trials register such as www.clinicaltrialsregister.eu?

  o Give figures for the enrolment rates
- A clear indication as to what is considered as structured data versus unstructured data early on in the manuscript.

- Would it be possible in the supplementary files to have in addition to the listed criteria in French an English translation?

- Under "Completeness" highlight the main points from additional file 3.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Unable to assess

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

'I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal