Tigran Arzumanov[a]*, Andreas Walter[b], Barış Erdoğan[c], and Luis Magalhaes[d]

Matching Clinical Trials with Patients: Global Patient Search and Identification using De-identified EHRs

a. Head of Sales, Clinerion Ltd, Margarethenstrasse 47, CH-4053 Basel, Switzerland, E-mail: tigran.arzumanov@clinerion.com *
b. Chief Technology Officer, Clinerion Ltd., Margarethenstrasse 47, CH-4053 Basel, Switzerland, E-mail: andreas.walter@clinerion.com
c. Head of EEMEA Region, Clinerion TurkeyTeknoloji Arastirma Ltd. Sti., Uphill Towers A-87 Batı, Ataşehir, İstanbul, Türkiye, E-mail: baris.erdogan@clinerion.com
d. International Sales Manager, Clinerion Ltd,Margarethenstrasse 47, CH-4053 Basel, Switzerland, E-mail: luis.magalhaes@clinerion.com

1. Introduction

Patient recruitment for clinical trials is a well-known problem: delays in patient recruitment are the most prominent reason for clinical trial delays.

- Up to 50% of all delays are caused by slow recruitment[1].
- 30% of phase III terminations are caused by recruitment difficulties[2].
- 48% of sites miss their enrollment targets for Phase II or III studies, making timelines nearly twice as long as planned[3].
- Each day a drug is delayed from reaching the market, the pharmaceutical company loses up to $8 million[4].

Such delays affect the entire drug development process:

- Suffering of patients due to delays in bringing innovative drugs to market.
- Costing pharma companies lost revenues in missed drug launch dates.

These challenges could be overcome by introducing a technology-assisted process for finding and identifying patients who could benefit from inclusion in a clinical trial.

Fig. 1: The clinical trials process for drug development.

References

[1] Cutting Edge Information, 2011
[2] Howes M, "The Pulse on Global Trials", CWWeekly, pp 6 (March 2014).
[3] Getz K, LambertiMJ, "89% of trials meet enrollment, but timelines slip, half of sites under-enroll", Tufts CSDD Impact Report, Vol. 15, No. 1 (January/February 2013).
[4] "The Expanding Web of Clinical Trial Patient Recruitment", ISR Reports (March 2014).

2. Methods

Clinerion's technology solution allows the simultaneous search of patients in multiple hospitals from a central location. Each participating hospital operates a dedicated server connected to the federated server network.

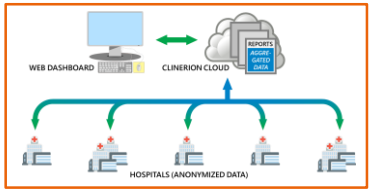

Fig. 2: Clinerion's technology solution is a highly scalable hybrid cloud and federated server network.

Leading edge, proprietary big data analytics in a hybrid infrastructure offers real-time search across multiple networked electronic health record systems made interoperable by the use of semantic and ontology methods.

Clinerion's technology solution is protected by patent:

- "Semantic Interoperability System for Medicinal Information" (U.S. Patent US20130030827 A1, publication date: January 31, 2013), is used in the semantic search and indexing component at the backend of the Clinerion technology solution.
- „Patientenrekrutierungssystem" (EPA PCT patent Clin 11043 WO, filing date: August 4, 2017), defines the "anonymized identification" (ANID) technology, which outlines a method by which the anonymized patient medical records which fit a trial protocol can be matched by authorized hospital trial staff against the original records to identify eligible patients.

The Clinerion technology solution accelerates the process at the key steps of trial protocol development, feasibility analysis, and patient identification. A pharma company sponsoring a trial can leverage the EHR-data at hospitals to find trial sites with eligible patients in one seamless, real-time process, from protocol design, to site selection, to patient search and identification.

2.1. Site Feasibility – a pharmaceutical company uses Clinerion's technology solution to assess the number of patients at potential clinical trial sites. With it, a study protocol can be queried at all the servers in the hospital network, simultaneously, returning aggregated counts.

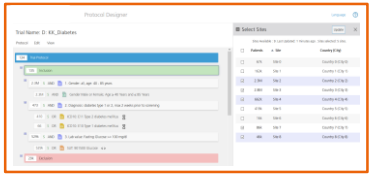

Fig. 3: The Protocol Designer: multi-dimensional protocol definition with five dimensions of query and unlimited criteria.

2.2. Patient Identification – a trial nurse at the hospital may see the corresponding list of candidates. The patient can be re-identified for enrollment through the usual process.

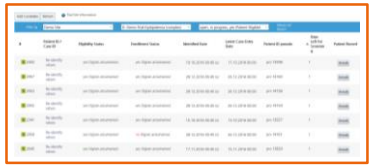

Fig. 4: Trial staff receive a list of eligible candidates to screen and validate.

Fig. 5: Example histogram of patient statistics generated by the Clinerion technology solution.

2.3. Real-Time Patient Search and Identification – the query keeps running during the trial and alerts the study nurse of new, suitable patients, in real-time.

2.4. Patient Privacy and Data Security – patient privacy is secured by use of "anonymized identification" (ANID) technology and by ensuring identifiable patient data does not leave the hospital. Data security is ensured by multiple firewalls, one-way data connections and authentication for users.

- The Clinerion technology solution is fully compliant with data privacy regulations in the USA (HIPAA), the EU (Directive 95/46/EC) and the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679).

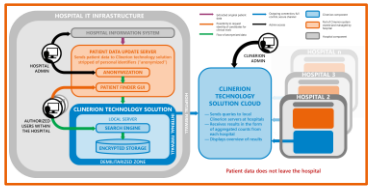

Fig. 6: Patient privacy and data security

3. Results

As of January 2018, 97 studies have been conducted using the Clinerion technology solution.

Fig. 7: Results of feasibility and recruitment studies performed using Clinerion technology solution vs. numbers estimated by hospital trial staff.

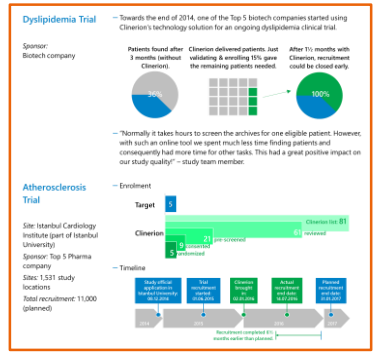

Fig. 8: Results from two trials show that Clinerion's technology solution can find eligible patients more rigorously and quicker than doing a manual search following normal procedures.

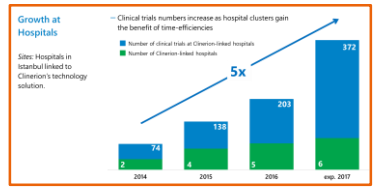

Fig. 9: Clinerion-connected hospitals have seen an increase in trials placed at their sites.

4. Conclusions

The electronic Clinerion technology solution for clinical trials addresses the critical barrier of slow patient recruitment. The system enables search and identification of suitable clinical trial candidates using the electronic records of multiple hospitals - in real time. The system has been shown to find 10-30x more patients, and quicker, than traditional methods.