Cost-Benefit Assessment of the Electronic Health Records for Clinical Research (EHR4CR) European Project

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ABSTRACT

Objective

The widespread adoption of electronic health records (EHR) provides a unique and novel opportunity to improve the efficiency of clinical research processes. The European EHR4CR (*Electronic Health Records for Clinical Research*) 4-year project has developed a technological platform to enable the reuse of EHR data for clinical research. The objective of this cost-benefit assessment (CBA) is to assess the value of EHR4CR solutions compared to current practices.

Methods

Three clinical research scenarios were selected: Protocol feasibility assessment (S1), patient identification for recruitment (S2), and clinical study conduct (S3). The approach considered that the estimated reduction in actual person-time and costs of performing EHR4CR S1, S2, S3 applied to a Phase II or Phase III oncology clinical trial as a reference case would accelerate time to market (TTM). Probabilistic sensitivity analyses were conducted.

Results

When converting the efficiency gains realized with the EHR4CR platform into potential financial value for achieving faster TTM, the absolute mean cost-benefit for the global pharmaceutical oncology sector was estimated at €161m (S1), €46m (S2), €1'904m (S3), €204m (S1+S2), and up to €2'119m (S1+S2+S3) when the three scenarios were used sequentially.

Conclusions

The results confirm that optimizing clinical trial design and study conduct with the EHR4CR platform would generate substantial added value for pharmaceutical industry.

Disclosure

The EHR4CR project is mandated by the Innovative Medicines Initiative (IMI) co-funded by the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

BACKGROUND AND OBJECTIVE

Pharmaceutical innovation faces important research and development (R&D) challenges, including significant delays and escalating R&D costs.

- The average cost of developing a new drug is estimated at €1.2 billion[1].
- The average cost of clinical trials has increased three-fold over the last 12 years[2]
- Clinical development process is lengthy and can last 8 to 10 years[3,4].

Major R&D bottle necks include sub-optimal protocol designs, slow patient recruitment, and labor-intensive and time-consuming clinical study conduct.

- On average, there are 2-3 protocol amendments implemented per clinical trial. This number exceeds 3.5 for Phase III clinical trials[5].
- Each protocol amendment takes an average additional 61 days to implement and costs over USD450'000[3]
- Almost half of all trial delays are caused by participant recruitment problems[6].
- 48% of sites miss their enrollment targets in Phase II and III multi-center study[7].
- The percentages of studies that complete enrolment on time are 18 % in Europe, 17 % in Asia-Pacific, 15% in Latin America, and 7 % in the US[6].
- Western Europe (69%) and Eastern Europe (75%) have the lowest achievement rates of targeted levels compared to North America (98%), Latin America and Asia Pacific[7].
- Over 70% of data are duplicated between institution's EHR and clinical trial systems[6].

Pharmaceutical industry must transform its R&D processes to deliver innovative medicines more efficiently by:

- Improving the feasibility assessment of clinical trial protocol;
- Enabling the identification of suitable patients and speeding up their recruitment;
- Accelerating clinical study conduct, including serious adverse events (SAEs) reporting.

The expected benefits of enhancing these clinical research scenarios are summarized in **Table I.**

Table I. Expected benefits of improving clinical research scenarios

Clinical Research Scenarios	Expected Benefits
Protocol feasibility assessment	▪ More patient-centric protocol ▪ Improved site and patient experience of study ▪ Avoidance or reduction of protocol amendments ▪ Increased probability of achieving the clinical trial objectives ▪ Reduced administrative burden of clinical research ▪ Significant reduction in actual person-time and costs ▪ Improved efficiency and reduced clinical trial cycle time
Patient identification and recruitment	▪ Better and faster patient and clinical site targeting ▪ Accelerated patient recruitment ▪ Increased probability of achieving the clinical trial endpoints ▪ Reduced administrative burden and clerical tasks ▪ Significant reduction in actual person-time and costs ▪ Improved efficiency and reduced clinical trial cycle time
Clinical study conduct and reporting of serious adverse events (SAE)	▪ Increased overall efficiency ▪ Clinical trial seamless execution (reduced paper work) ▪ High quality data and no data re-entry (reduced risk of error) ▪ Improved patient safety ▪ Significant reduction in actual person-time and costs ▪ Improved efficiency and reduced clinical trial cycle time

The EHR4CR European project, one of the largest public-private research partnership between the European Union and the EFPIA, has developed an advanced technological platform to enable the trustworthy reuse of hospital EHRs data for clinical research in Europe, and beyond. The objective of this CBA is to assess the potential value for pharmaceutical industry of adopting EHR4CR clinical research solutions versus current practices, as applied to oncology trials as a reference case.

METHODS

Using the perspective of pharmaceutical industry, for the first time, this CBA assesses the value of EHR4CR solutions compared to current practices for enhancing three clinical research scenarios (S), whether used separately, in combination, or in sequence, namely.

- Protocol feasibility assessment (S1),
- Patient identification and recruitment (S2), and
- Clinical study conduct and SAEs reporting (S3).

A resource utilization assessment was conducted by EFPIA partners to estimate the actual person-time and related costs for performing S1, S2, S3 under current practices and under EHR4CR conditions for a Phase II or Phase III clinical trial in oncology (reference case). For illustrative purposes, **Table II** summarizes the sum of the minimum and the sum of the maximum values of the estimated number of days and costs under current practices and under ERH4CR conditions.

Table II. Resource Utilization Assessment

	Estimated # Days saved in Actual Person-Time (∑Minimum – ∑Maximum)		Estimated Costs (€) (∑Minimum – ∑Maximum)	
Scenarios	**Current Practices**	**EHR4CR**	**Current Practices**	**EHR4CR***
S1: Protocol Feasibility Assessment	146.5-389	73.3-194.5	100'646 – 267'243	50'323-133'622
S2: Patient Identification and Recruitment	39.9-100.3	20.2-46.2	27'415 -68'907	13'880-31'741
S3: Study conduct and SAE	797.03-5'264.1	408.03-2'737.1	729'193-4'163'940	371'413-2'153'760

Source: EFPIA Partners Resource Utilization Assessment (2013) *: Excluding EHR4CR fees for service

The CBA assumptions **(Table III)** were validated by a multidisciplinary expert panel composed of academic experts, clinical research senior scientists (EFPIA partners), and expert health economists.

Table III. CBA Assumptions

- Global multicenter Phase II or Phase III oncology study
- Study conducted in 10-15 countries
- Involving 100-150 clinical centres
- Clinical study size: 450-1500 patients
- Full time equivalent (FTE) = €687/day (estimated weighted average daily wage)
- 1 FTE = 220 days
- 50% reduction in actual person-time and costs for S1,S2,S3 tasks impacted by the EHR4CR platform
- S1 assumes a reduction of 50% in the number of protocol amendments under EHR4CR conditions

Assuming that the estimated reduction in actual person-time and cost achieved with the EHR4CR platform would directly translate into accelerated TTM for oncology compounds, the potential mean benefits for the global pharmaceutical industry were derived by applying the full distribution of global market values (2012) of oncology products[8]. Absolute and relative CBA were conducted using probabilistic sensitivity analyses (10,000 Monte-Carlo simulations).

RESULTS

Compared to current practices, should the efficiency gains achieved with EHR4CR Scenarios 1, 2 and 3 used individually or in combination ultimately translate into achieving faster TTM, the corresponding estimated absolute cost-benefit for the global pharmaceutical oncology sector were derived, as described in Figure 1 and in **Table IV.**

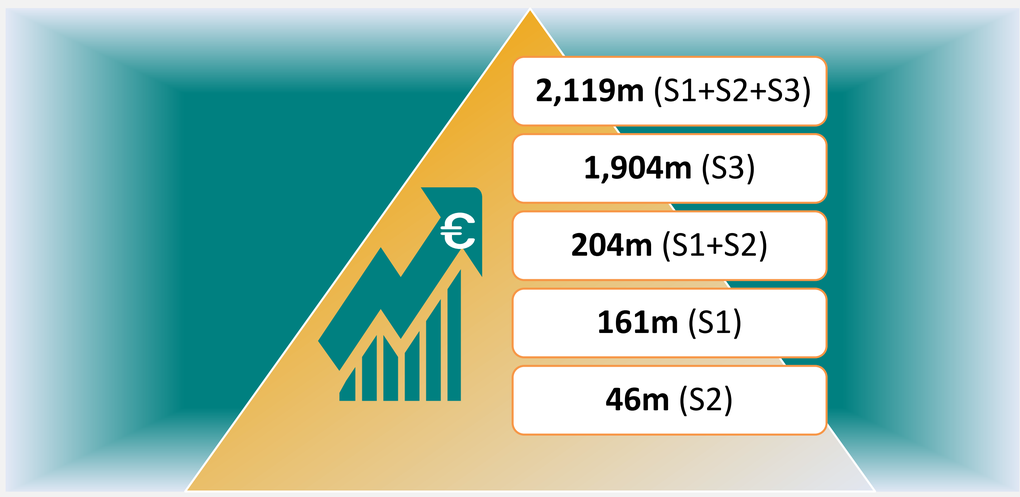

Figure 1. Estimated cost-benefit of EHR4CR clinical research scenarios

Table IV. Cost-Benefit Assessment Results

Scenarios	Mean Costs Current Practices (SD)	Mean Costs EHR4CR* (SD)	Mean Benefit (€)	Absolute Cost-Benefit§ (€)	Relative Cost-Benefit§§
(S1) Protocol Feasibility	183'959 (24'035)	216'491 (44'999)	161'522'390	-161'305'616	0.01
(S2) Patient identification and Recruitment	48'142 (7'162)	185'393 (51'078)	45'712'633	-45'527'322	0.02
(S3) Study conduct and SAE reporting	2'448'030 (690'712)	1'597'410' (361'624)	1'906'506'416	-1'904'911'265	0.01
S1+S2	-	402'111 (67'555)	204'573'175	-204'171'064	0.01
S1+ S2+ S3	-	1'999'261 (368'549)	2'121'810'208	-2'119'810'946	0.04

SD: Standard Deviation *: Based on a 50% reduction in actual person-time. Includes estimated EHR4CR fees for service §Absolute CBA (estimated costs minus benefits) §§ Relative CBA (estimated costs divided by benefits)

CONCLUSIONS

By enabling the trustworthy reuse of hospital-based EHR patient-level data for clinical research, the EHR4CR breakthrough platform promises to transform clinical research environments, to enhance current practices, and to improve the overall efficiency of clinical research current frameworks. This CBA is the first study to assess the value of the EHR4CR platform compared to current practices. The results confirm that the EHR4CR-enabled clinical research scenarios, whether used individually, in combination, or in sequence within a clinical trial workflow, appear highly efficient, reducing the actual person-time and operational costs for conducting Phase II-III clinical trials in oncology as the reference case. Should the efficiency gains realized with the EHR4CR platform translate into achieving marketing authorization faster, and delivering innovative medicines to healthcare sooner, this economic evaluation establishes that the overall benefits and added value to global pharmaceutical industry would be substantial. While these results suggest an early adoption of EHR4CR solutions, further research is warranted to assess the EHR4CR value in real life context, once the platform has been fully deployed for enhancing clinical research, across clinical trial phases and therapeutic areas, in Europe, and beyond.

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Disclaimer

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