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

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**Objective**

The widespread adoption of electronic health records (EHR) provides a unique and novel opportunity to improve the efficiency of all research activities. The European EHR4CR project aims to address these research questions associated with clinical research using EHRs. The European EHR4CR 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**

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 (S1, S2, and S3), whether (a) protocol feasibility assessment (S1), (b) patient identification and recruitment (S2), and (c) 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, and 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 EHR4CR conditions.

**RESULTS**

Table II: Resource Utilization Assessment

<table>
<thead>
<tr>
<th>Scenarios</th>
<th>Current Practices</th>
<th>EHR4CR</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1: Protocol Feasibility Assessment</td>
<td>146.2-373</td>
<td>193.7-314.5</td>
</tr>
<tr>
<td>S2: Patient Identification and Recruitment</td>
<td>59.9-100.3</td>
<td>26.2-46.2</td>
</tr>
<tr>
<td>S3: Study Conduct and SAE Reporting</td>
<td>79.03-129.0</td>
<td>82.68-91.9</td>
</tr>
</tbody>
</table>

**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 EHR4CR solutions compared to current practices. The results confirm that the EHR4CR-enabled research clinical trials were found to be more efficient, reducing the actual person-time and operational costs for conducting Phase II clinical trials in oncology as a reference case. Should the efficiency gains realized with the EHR4CR platform translate into enhancing marketing authorization faster, and delivering innovative medicines to healthcare sooner, this economic evaluation, in combination with current EHR 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.

**References**

2 Waller A. The cost of clinical trials. Drug Discovery & Development 2005, May 18
5 Alexander M. A Survey of the Costs of Clinical Development. CRO Insights Apr 2011

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