

Master thesis with Bayer Vital GmbH

Title	Health economic consequences of EHR2EDC integration into clinical studies
Description	<p>Today, the standard for an investigator participating in primary data collection is double documentation into practice management systems (PMS) or hospital information systems (HIS) and additionally into electronic data capture (EDC) systems, to comply with the needs of pharmaceutical industry and the requirements of regulatory bodies.</p> <p>In particular, automation of the transfer process of health data captured in electronic health records (EHRs) in clinical practice and data required in EDC systems for clinical research defined as EHR to EDC (EHR2EDC) needs to be resolved.</p> <p>One relevant aspect is the health economic consequence of this shift, especially the incentives for investigators, the definition of a fair market value, the willingness to participate, factors influencing EHR2EDC and its compensation and the change from pay for time to pay for data items.</p> <p>The aim of this research is to develop a model to compare pay for time and pay for data item approach with existing compensation data in Phase-IV studies, to perform a sensitivity analysis, and to identify relevant factors of willingness of participation. Testing of modifying these factors in real-life setting will not be part of this research, but the next scientific step.</p>
Type of research	Conceptual, quantitative
Data source(s)	Fair Market Value Assessments Study Case Report Forms (CRFs) Investigator contracts
Does the student have to collect data?	No
Research method(s)	Conceptual work, quantitative analysis
Related courses	Health economics, Health care management
Skill(s) required	Good analytical skills Knowledge of health economics concepts
Background reading	<p>Müller, C.; Herrmann, P.; Cichos, S.; Remes, B.; Junker, E.; Hastenteufel, T.; Mundhenke, M. (2023). Automated Electronic Health Record to Electronic Data Capture Transfer in Clinical Studies in the German Health Care System: Feasibility Study and Gap Analysis. <i>J Med Internet Res</i>; 25:e47958 doi: 10.2196/47958</p> <p>FSA-Kodex zur Zusammenarbeit mit Fachkreisen („FSA-Kodex Fachkreise“) geändert am 14.11.2019 (bekannt gemacht im Bundesanzeiger vom 30.03.2020, BAnz. AT 30.03.2020 B4)</p>

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