

# EHR Definition

Is a Laboratory Analyzer an EHR<sup>1</sup>?  
Is a POCT Device an EHR<sup>1</sup>?

<sup>1</sup> according to EHDS

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Working Group Meeting  
1-5 December 2025  
Cologne, Germany

# Is a Laboratory Analyzer or a POCT Device an EHR according to EHDS?

# Let's Ask notebookLM - what is an EHR<sup>1</sup>

An EHR system (electronic health record system) is defined by the EHDS Regulation as:

1. **Any system**, consisting of software or a combination of hardware and software.
2. It **allows the processing** (storing, importing, exporting, editing, or viewing) of personal electronic health data belonging to defined **priority categories**.
3. The system must be **intended by the manufacturer** for use by **healthcare providers** when providing patient care.
4. Alternatively, it is intended for use by **patients accessing their electronic health data**; this definition is intentionally wide to ensure interoperability throughout connected systems.

# Let's Ask notebookLM - Laboratory Analyzer<sup>2</sup>

A laboratory analyzer may be considered an EHR system based on the definition in the sources, but only if specific conditions regarding its function and intent are met:

1. An **EHR system** is defined as any system, including software or a combination of hardware and software, that processes (stores, exports, imports, edits, or views) personal electronic health data belonging to the priority categories.
2. "Medical test results, including laboratory... results and related reports," constitute one of the defined priority categories of personal electronic health data.
3. A laboratory analyzer is identified as an observation device whose information is part of the laboratory result data elements.
4. If the analyzer's software handles the processing of these results and is intended by the manufacturer for use by healthcare providers when providing patient care, it is included in the EHR system definition, which is intentionally wide to cover systems "feeding" aggregate hospital systems.

# Let's Ask notebookLM - POCT Device<sup>3</sup>

Yes, a Point of Care Testing (POCT) Device can be considered an EHR system, provided it meets the functional criteria set out in the definition:

1. POCT devices generate **medical test results**, which are explicitly listed as a **priority category** of personal electronic health data.
2. An EHR system is defined widely as any software or combination of hardware and software that allows processing (storing, exporting, editing, or viewing) these priority data categories.
3. For the system to qualify as an EHR, the manufacturer must intend it for use by healthcare providers when delivering patient care or by patients accessing their health data.
4. Since the definition is intentionally **wide**, covering systems that "feed" aggregated hospital systems, a POCT device processing these results is generally included if the intent requirement is met.

# But ... what do we think?

Is a POCT Device an EHR?

- It is used by healthcare providers providing patient care...
- ... but isn't it only a measuring devices with not enough knowledge of the patient to be considered an EHR?

# But ... what do we think?

Is a Laboratory Analyzer an EHR?

- It is used by laboratory professionals to generate observations which in the end are used by healthcare professionals providing patient care...
- ... but isn't it only a measuring devices with not enough knowledge of the patient to be considered an EHR?

# The prompts

- <sup>1</sup> “what is an EHR according to ehds in 4 short statements?”
- <sup>2</sup> “is a laboratory analyzer by this definition an EHR in maximum 4 short statements”
- <sup>3</sup> “is a Point of Care Testing Device by this definition an EHR in maximum 4 short statements”