

Strengthening signal detection during a pandemic with additional casuistry from electronic health records using a natural language processing tool

Background

The spontaneous reporting system (SRS) remains the cornerstone for pharmacovigilance to safeguard post-marketing drug safety. However, the SRS is not immune to limitations. These include, among others, the voluntary nature of reporting suspected adverse drug reactions (ADRs). Consequently, this delays the signal detection process. Nevertheless, comprehensive and real-time patient information, including potential ADR observations, is documented by HCPs in electronic health records (EHRs). Targeted search in these observations in EHRs to identify additional suspected ADR cases for safety signal detection is independent from the interpreted causation, motivation, and available time of the reporting HCP and, hence, a proactive additional method in signal detection.

Objectives

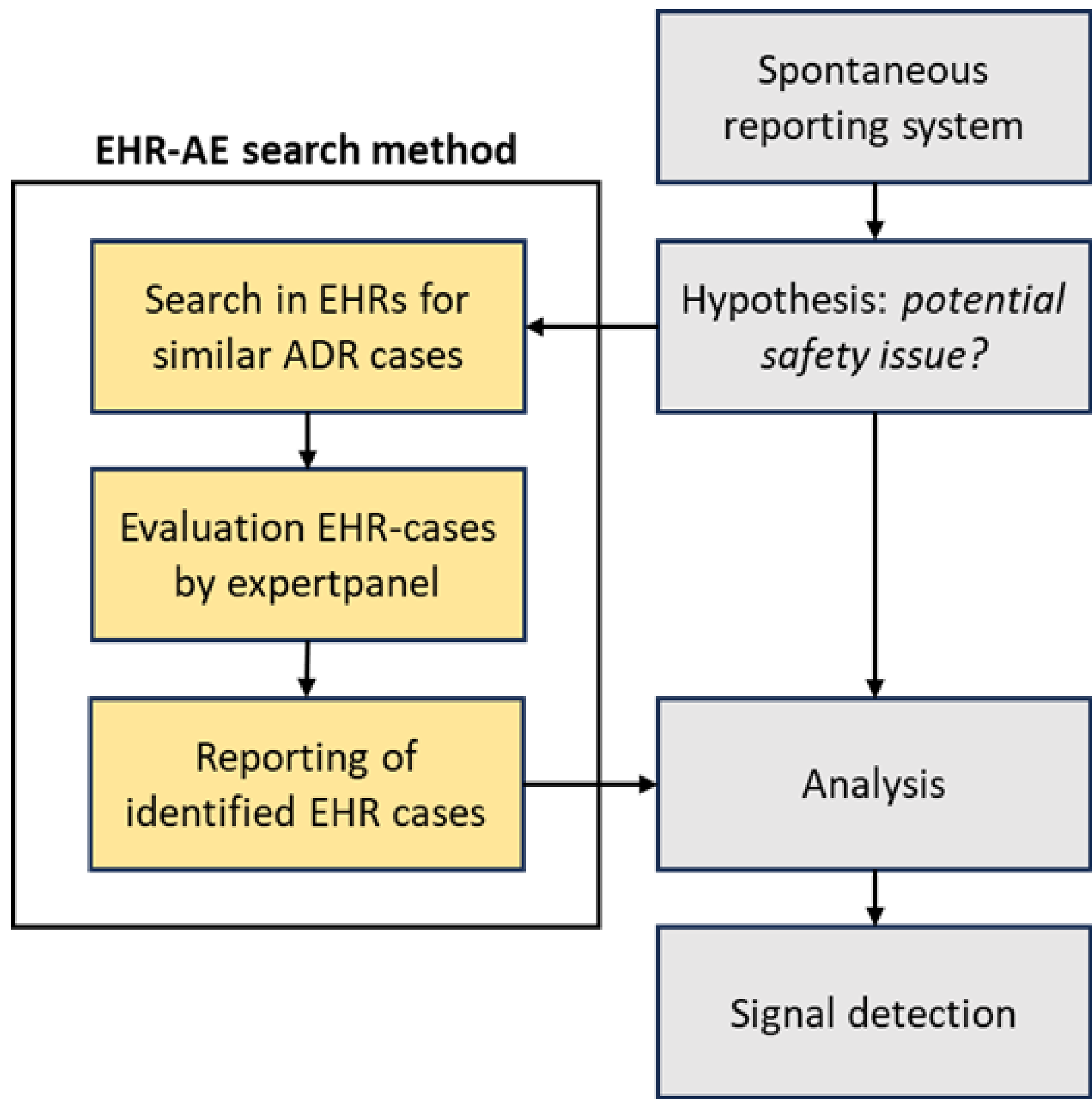
EHR-AE search method

Evaluate the added value of targeted searches in EHRs to identify additional suspected ADR cases. The added value of this EHR-AE search method is evaluated based on:

1. Feasibility of identifying ADR cases using the EHR-AE search method
2. Detection of safety signals using additional EHR cases
3. Acceleration of safety signal detection using additional EHR cases

Method

Information derived from spontaneous reports, related to potential drug safety concerns, is used to (1) formulate queries within a natural language processing tool to identify additional cases within EHRs that align with the existing drug safety concerns. Identified EHR cases undergo (2) review by an expert panel, comprising HCPs and pharmacovigilance experts, before (3) being reported to Lareb's SRS. Thereafter, these identified EHR cases are (4) analyzed alongside the received spontaneous reports, which correspond to the same potential COVID-19 vaccine safety risk, to strengthen the signal detection process of that safety risk.



Results

Objective 1. For 6 out of 13 performed searches concerning different COVID-19 vaccine-ADR associations, at least 1 ADR-case was identified. In total 41 suspected ADR cases were identified in EHRs and reported to Lareb.

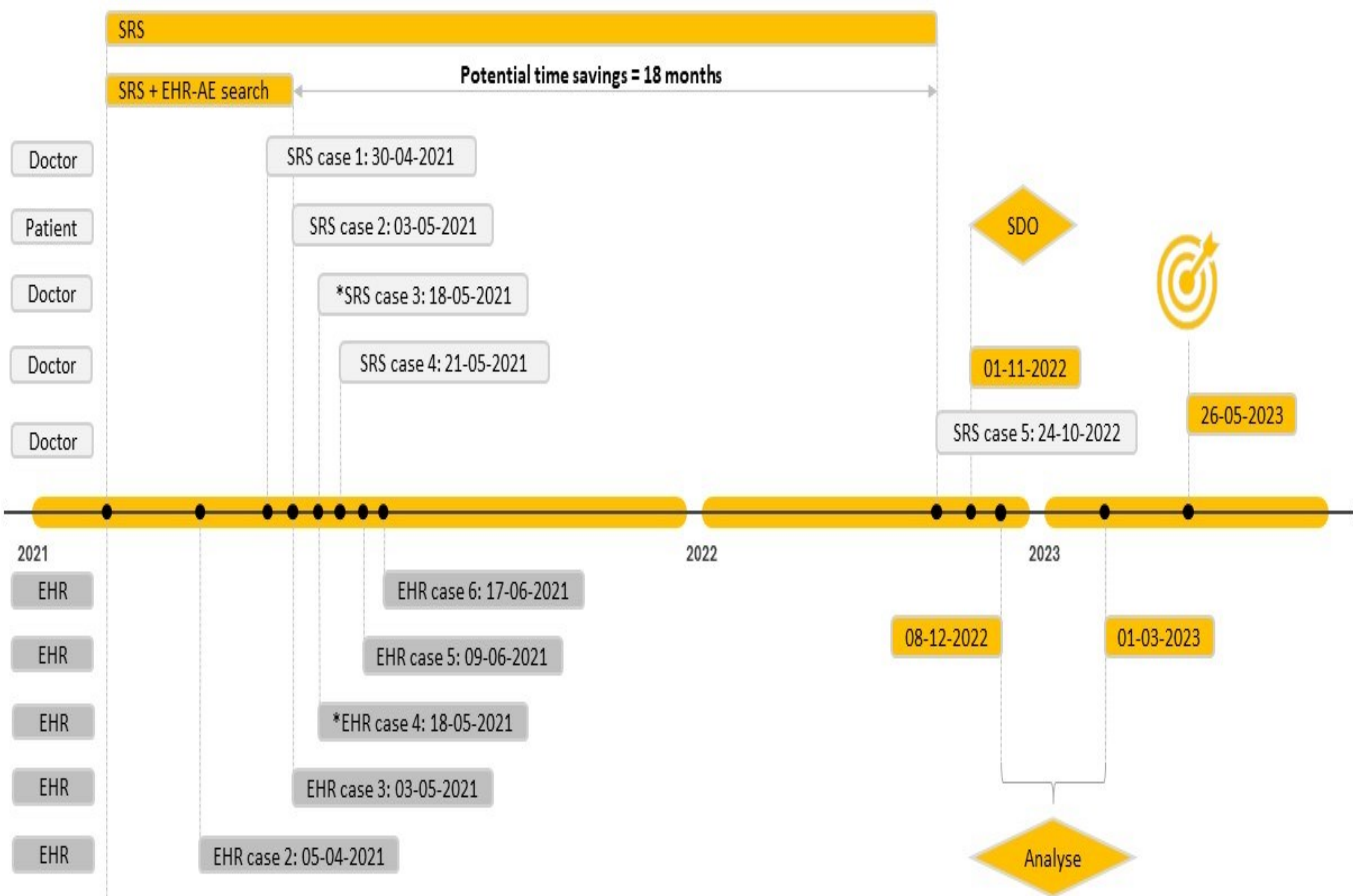
Objective 2. Reported suspected ADR cases identified from EHRs contributed to 2 detected signals: AIHA and Sudden deafness following COVID-19 vaccination.

Objective 3. One signal concerning AIHA associated with COVID-19 vaccines potentially could have been detected 18 months earlier. Another signal concerning ITP associated with COVID-19 vaccines could have been detected 2 months earlier.

Objective 1 & 2: conducted EHR searches and ADR-case finding

(Potential) ADRs associated with COVID-19 vaccination	EHR cases meeting search criteria (1)	After context screening (2)	After EHR verification (3)	After expert panel assessment (4)
Acute macular retinopathy	23	0% (0)	0% (0)	0% (0)
Antiphospholipid syndrome	465	3% (15)	2% (8)	2% (7)
Antisynthetase syndrome	58	0% (0)	0% (0)	0% (0)
Autoimmune haemolytic anaemia	195	6% (12)	5% (9)	3% (6)
Capillary leak syndrome	10	20% (2)	0% (0)	0% (0)
Guillain-Barré syndrome	91	16% (15)	4% (4)	4% (4)
Immune thrombocytopenic purpura	457	7% (31)	3% (14)	3% (14)
Minimal change nephropathy	142	6% (8)	1% (1)	0% (0)
Myelitis transverse	120	7% (8)	2% (2)	2% (2)
Postural orthostatic tachycardia syndrome	53	8% (4)	4% (2)	0% (0)
Sudden deafness	235	6% (15)	3% (8)	3% (8)
Susac syndrome	11	18% (2)	0% (0)	0% (0)
Reduced Von Willebrand Factor activity	208	6% (13)	1% (3)	0% (0)
Total	2068	6% (125)	2% (51)	2% (41)

Objective 3: signal acceleration of AIHA associated with COVID-19 vaccines



Conclusions

1. The EHR-AE search method enables identification of suspected ADR cases in EHRs,
2. Identified suspected ADR cases from EHRs can contribute to signal detection,
3. Identified suspected ADR cases from EHRs can accelerate signal detection .