Transfusion & Immunization
Adverse Event FHIR IG
Session Presentations

HL7 Connectathon January 14, 2021

Jean Duteau (jean@duteaudesign.com)
Will Rosenfeld (wtrosenf@us.ibm.com)
Transfusion and Immunization Adverse Event Track

Overview

- Our IG provides profiles for generating AE case reports for biologic products
- Developed by IBM as part of the FDA CBER Biologics Effectiveness and Safety (BEST) initiative and balloted through BR&R

Materials

- IG: https://build.fhir.org/ig/HL7/fhir-icsr-ae-reporting/branches/main/index.html
- Track: https://confluence.hl7.org/display/FHIR/2021-01+Transfusion+and+Immunization+Adverse+Event+Track

Agenda

- Session 1 (11am ET): Technical demo generating an ICSR using a SMART app and validating with our IG
- Session 2 (3pm ET): Clinical and regulatory discussion of IG input and output mappings

Contacts

- Jean Duteau (jean@duteaudesign.com)
- Shayan Hobbi (shayan.hobbi@ibm.com)
- Will Rosenfeld (wtrosenf@us.ibm.com)
- Hussein Ezzeldin (hussein.ezzeldin@fda.hhs.gov)
Session Details

- Generate a VAERS individual case safety report (ICSR) from synthetic EHR FHIR data using the BEST SMART chart review tool developed by IBM and FDA
- Convert and validate ICSR against the IG’s FHIR profiles
- Discussion with track participants about how EHRs will generate cases from FHIR data

Suggested Participants

EHR Vendors, public health agencies, and researchers
Transfusion and Immunization Adverse Event Track – Session 1 SMART App Demo

Agenda

1. Introduction [5 min]
2. IG Overview [10 min]
3. Case Report Generation Demo [15 min]
4. IG Validation Demo [15 min]
5. Q&A [15 min]
Introduction: Presenters

Jean Duteau  
*Duteau Design*

Will Rosenfeld  
*IBM*

Shayan Hobbi  
*IBM*

Jeff Beers, MD  
*IBM*
This effort is sponsored by the FDA Center for Biologics Evaluation and Research (CBER) through the BEST initiative and developed by our IBM-led team.

https://www.bestinitiative.org/
• **Adverse Event**: Any untoward medical occurrence (i.e., outcome) which does not necessarily have a causal relationship with treatment (i.e., biologic)

• **Biologic Product**: Vaccines, blood, tissue, cellular, gene, and xenotransplantation products

• **VAERS**: Vaccine Adverse Event Reporting System – specific for vaccines

• **FAERS**: FDA Adverse Event Reporting System – covers all other drugs and products

• **ICSR**: Individual Case Safety Report – specification for AE report data

• **ISBT-128**: International standard for medical products of human origin
Problem Statement

• **Challenge**: Current adverse event reporting processes are manual/burdensome due to a lack interoperability between EHR and reporting systems

• **Objective**: Improve data interoperability for automating post-market adverse event reporting processes
Transfusion and Immunization Adverse Event Track – Session 1 SMART App Demo

IG Overview

• **Name:** Profiles for ICSR Transfusion and Vaccination Adverse Event Detection and Reporting

• **Workgroup Sponsor:** Biomedical Research and Regulation (BR&R)

• **Links:**
Case Generation Demo

To begin, we will demonstrate the case generation capabilities of the BEST Adverse Event Reporting Automation prototype (infrastructure diagram below)
Data Connection: Chart review SMART app supports connections to the Cerner, Epic, HSPC, and Smart Health IT sandboxes

Case Report Generation Demo

Note: Data shown in demonstration are synthetic.
Transfusion and Immunization Adverse Event Track – Session 1 SMART App Demo

Case Report Generation Demo

**Review and Generation:** Demo of reviewing case data, followed by the generation of a VAERS and FAERS case report

*Note: Data shown in demonstration are synthetic.*
Validation: ICSR generation, cases can be converted into FHIR format and validated using our FHIR IG

Note: Data shown in demonstration are synthetic.
Transfusion and Immunization Adverse Event Track – Session 1 SMART App Demo

Acknowledgements

**FDA**
- Steven Anderson
- Hussein Ezzeldin
- Barbee Whitaker
- Manette Niu
- Jane Mutanga
- Alan Williams
- Judy Richardson

**IBM and Partners**
- Jean Duteau
- Shayan Hobbi
- Will Rosenfeld
- Jeff Beers
- Anna Podgornyak
- Kathryn Edwards
- Chet Andrzejewski
- Joseph Blumenthal
Transfusion and Immunization Adverse Event Track – Session 1 SMART App Demo

Question & Answer

• Q&A:
  – Via Whova App: https://whova.com/portal/webapp/hlsfh_202101/Agenda/1436592
  – Via Zulip: https://chat.fhir.org/#narrow/stream/265424-icsr-on-fhir
  – Via Zoom: Chat
  – Via Email: wtrosenf@us.ibm.com and jeanduteau@design.com
Session Details

- Review data inputs from EHR to ICSR and request clinical feedback
- Review data outputs of ICSR and request public health feedback
- Review representation of transfusion information
- Review AdverseEvent terminologies

Suggested Participants

Clinicians, public health agencies, and researchers
Transfusion and Immunization Adverse Event Track – Session 2 IG Mapping and Profiles

Agenda

1. Introduction [10 min]
2. Review EHR to ICSR inputs for clinical feedback [10 min]
3. Review ICSR outputs for public health feedback [10 min]
4. Review representation of transfusion information [10 min]
5. Review AdverseEvent terminologies [10 min]
6. Q&A [10 min]
Transfusion and Immunization Adverse Event Track – Session 2 IG Mapping and Profiles

Introduction: Presenters

Jean Duteau  
*Duteau Design*

Will Rosenfeld  
*IBM*

Shayan Hobbi  
*IBM*
Transfusion and Immunization Adverse Event Track – Session 2 IG Mapping and Profiles

Introduction: Sponsoring Initiative

This effort is sponsored by the FDA Center for Biologics Evaluation and Research (CBER) through the BEST initiative and developed by our IBM-led team.

https://www.bestinitiative.org/

CBER Biologics Effectiveness and Safety (BEST) System

The Biologics Effectiveness and Safety (BEST) System was launched in October 2017 to expand and enhance CBER access to new and better data sources, methods, tools, expertise and infrastructure to conduct surveillance and epidemiologic studies. BEST is part of the Sentinel initiative and it promotes CBER’s Office of Biostatistics and Epidemiology’s (OBE) mission to assure the safety and effectiveness of biologic products including vaccines, blood and blood products, tissues and advanced therapeutics.
**Terminology**

- **Adverse Event**: Any untoward medical occurrence (i.e., outcome) which does not necessarily have a causal relationship with treatment (i.e., biologic)

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Transfusion and Immunization Adverse Event Track – Session 2 IG Mapping and Profiles

IG Overview

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- **Workgroup Sponsor**: Biomedical Research and Regulation (BR&R)

- **Links**:
Introduction: Gaps between surveillance needs and USCDI

Resources

• Submitted to USCDI: Submitted MedicationAdministration (L2), BiologicallyDerivedProduct (L1), AdverseEvent (Comment) via ONDEC

Data Elements

• MustSupport: ISBT-128 codes (for blood and tissues) and NDC codes (for vaccines and other biologic products) to sufficiently capture granular product details
Objective: To review EHR data inputs into the ICSR standard to obtain feedback from clinical and other stakeholders

5.19.1 Resource Profile: ICSR Composition

<table>
<thead>
<tr>
<th>Name</th>
<th>ICSRComposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>ICSR Composition</td>
</tr>
<tr>
<td>Status</td>
<td>Active as of 2021-10-18T18:50:21+00:00</td>
</tr>
<tr>
<td>Definition</td>
<td>The fields needed to represent the document metadata of an ICSR Report.</td>
</tr>
<tr>
<td>Source Resource</td>
<td>XML / JSON / Turtle</td>
</tr>
</tbody>
</table>

The official URL for this profile is:

http://hl7.org/fhir/us/icd-ae-reporting/StructureDefinition/icd-ae-icdcomposition

5.19.1.1 Formal Views of Profile Content

Description of Profiles, Differentiable, Snapshots and how the different presentations work.

<table>
<thead>
<tr>
<th>Name</th>
<th>Flags</th>
<th>Card. Type</th>
<th>Description &amp; Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition</td>
<td>0..*</td>
<td>Composition</td>
<td>A set of resources composed into a single coherent clinical statement with clinical semantics</td>
</tr>
<tr>
<td>- extension</td>
<td>4..*</td>
<td>Extension</td>
<td></td>
</tr>
<tr>
<td>- icd-ae-icd-extensionIndications</td>
<td>0..1</td>
<td>date/time</td>
<td>Extension Id: Unordered, Open by association</td>
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<tr>
<td>- icd-ae-icd-extensionIndications</td>
<td>0..1</td>
<td>date/time</td>
<td>Extension Id: Unordered, Open by association</td>
</tr>
<tr>
<td>- icd-ae-icd-extensionIndications</td>
<td>1..1</td>
<td>(Complex)</td>
<td>Extension Id: Unordered, Open by association</td>
</tr>
</tbody>
</table>

[current page image]
Objective: To review ICSR profiles to obtain feedback from public health and other stakeholders.
Objective: To review the IG’s representation of transfusion information using Procedure and BiologicallyDerivedProduct resources

8.24.1 Resource Profile: ICSR Transfusion

| Version      | 0.1.0                              |
| Name         | ICSRTransfusion                    |
| Title        | ICSR Transfusion                   |
| Status       | Active as of 2021-01-13T18:50:21+06:00 |
| Definition   | The common fields needed to represent a transfusion. |
| Source Resource | XML / JSON / Turtle |

The official URL for this profile is:

Objective: To review the IG’s AdverseEvent Profiles
Objective: To discuss plan to incorporate BEST adverse event detection algorithm logic into the IG
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Question & Answer

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  - Via Zulip: [https://chat.fhir.org/#narrow/stream/265424-icsr-on-fhir](https://chat.fhir.org/#narrow/stream/265424-icsr-on-fhir)
  - Via Zoom: Chat
  - Via Email: wtrosenf@us.ibm.com and jean@duteaudesign.com