http://hl7.org/fhir/uv/pddi/2018Sep/index.html

Potential Drug-Drug Interaction (PDDI) CDS IG : STU Ballot 1

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This is a pre-release version (Ballot 1) of Potential Drug-Drug Interaction (PDDI) CDS R1/STU. There is no current official version.
For a full list of available versions, see the Directory of published versions.

- **TODO** Citations in Vancouver please

1.0.0 Implementation Guide for PDDI CDS (DRAFT)

1.1.0 Introduction

This implementation guide is targeted at stakeholders who seek to increase the specificity and clinical relevance of potential drug-drug interaction (PDDI) alerts presented through the electronic health record. The approach is service-oriented and uses Web standards, a PDDI minimum information model, and emerging Health Information Technology (HIT) standards including CDS Hooks, Fast Health Interoperability Resources (FHIR), and Clinical Quality Language (CQL).

Contents

1.2.0 Collaborators and Funding

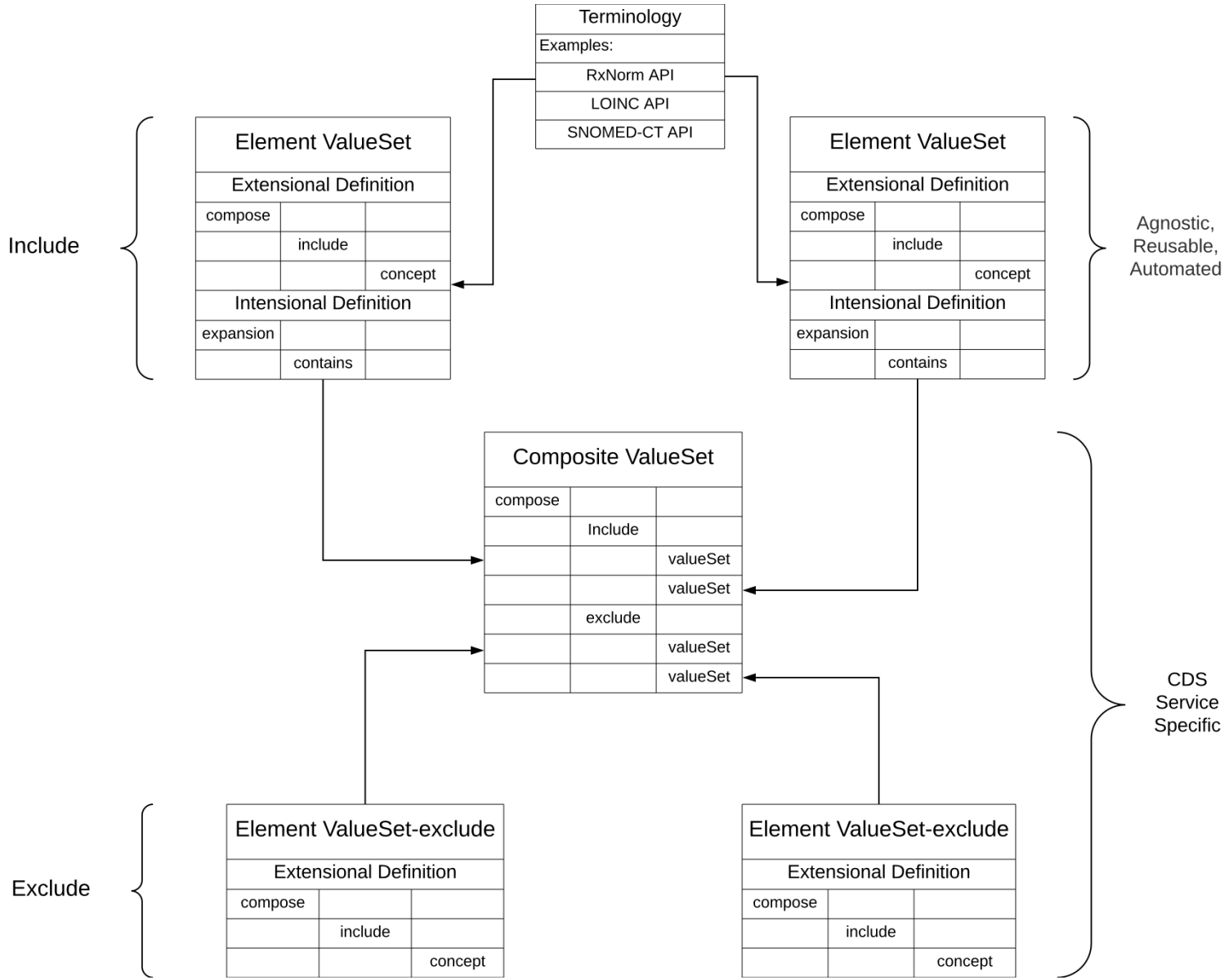
This implementation guide was developed by the Health Level 7 (HL7) Clinical Decision Support Work Group CDS WG in collaboration with the University of Pittsburgh Medical Center (UPMC), RWTH Aachen University, the Open Source Electronic Health Alliance (OSEHRA), the University of Arizona, and Wolters Kluwer Health. It was funded by AHRQ grants: R01 LM011838, R21 HS023826 and R01 HS025984, and NLM grant T15 LM007124.

PSS summary: http://wiki.hl7.org/index.php?title=PDDI-CDS_FHIR_IG_Proposal

Take home points for the current PDDI CDS IG

- Terminology - enables a full range of value sets at international scope using three components
  - Composite ValueSet, Element ValueSet, Element ValueSet-exclude
  - Examples with NSAIDS, PPIs, Loop Diuretics

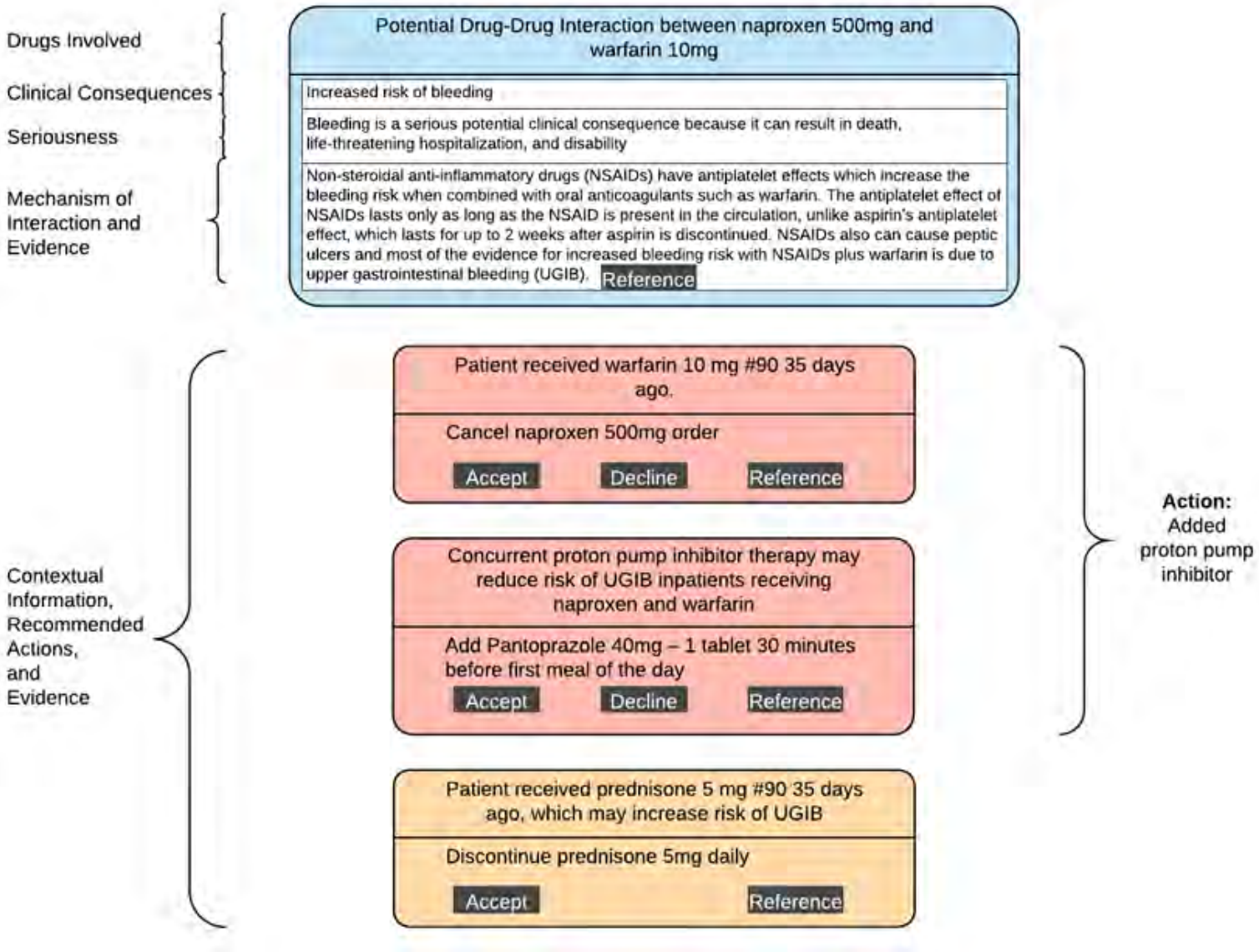
Terminology overview



Take home points …

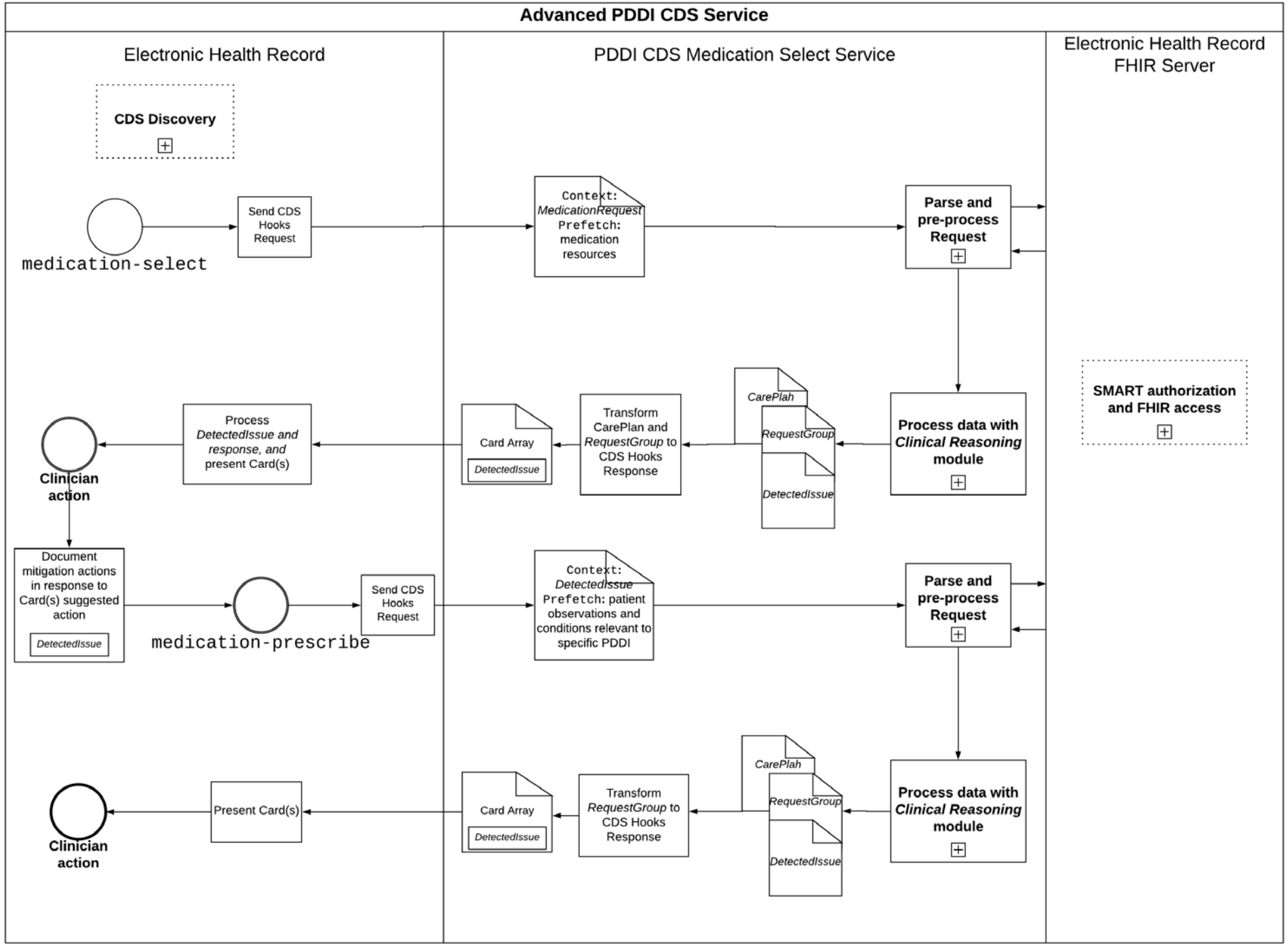
- Employs CDS Hooks ability to return multiple cards at once
  - All responses will have a purely informational card
    - Concordant with the W3C PDDI Min Info Model
      - Drugs involved
      - Clinical consequences
      - Serious?
      - Mechanism of interaction
        - evidence
      - Contextual information
        - Recommended actions and evidence
  - Some responses will have action cards for create, update, delete

Use of multiple cards example….



Take home points ….

- Two levels of CDS implementation
  - Level 1 : at time of medication order signature
    - Currently using CDS Hook ‘medication-prescribe’
  - Level 2 : at time of medication order selection
    - Adding support for a new CDS Hook ‘medication-select’


Advanced PDDI CDS Service
Electronic Health Record
PDDI CDS Medication Select Service
Electronic Health Record FHIR Server
CDS Discovery
medication-select
Send CDS Hooks Request
Context: MedicationRequest
Prefetch: medication resources
Parse and pre-process Request
SMART authorization and FHIR access
CarePlan
RequestGroup
DetectedIssue
Process data with Clinical Reasoning module
Transform CarePlan and RequestGroup to CDS Hooks Response
Card Array
DetectedIssue
Process DetectedIssue and response, and present Card(s)
Clinician action
Document mitigation actions in response to Card(s) suggested action
DetectedIssue
medication-prescribe
Send CDS Hooks Request
Context: DetectedIssue
Prefetch: patient observations and conditions relevant to specific PDDI
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CarePlan
RequestGroup
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Process data with Clinical Reasoning module
Transform RequestGroup to CDS Hooks Response
Card Array
DetectedIssue
Present Card(s)
Clinician action

Take home points …

- Shows how to use CQL with FHIR Library and PlanDefinition resources to implement PDDI CDS as a service using CDS Hooks
  - Functioning example using FHIR STU3, Hooks 1.0, and DBCG CQF-Ruler
    - http://dbmi-icode-01.dbmi.pitt.edu:8080/cds-services
  - Two exemplar interactions : warfarin – NSAIDS and digoxin – cyclosporine

IG STU Ballot 1 – summary

- Total reviewers = 3
- Total comments = 11
- Technical fixes = 10

IG STU Ballot 1 – comments

https://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=

- 18804 : IG authors to assess the status of response artifacts and relationship to DetectedIssue.

- Minor word changes, spelling, and link fixes
  - 18805 : Fix link
  - 18806 : All artifacts links need to point to the correct artifacts. IG authors to accomplish this
  - 18807 : Fix links
  - 18056 : Get more information from the comment submitter about the pages in question
  - 18057 : To be fixed as part of document Q/A
  - 18078 : Choose an option and revise the IG to include
  - 18079 : Move statement from 6.1.0 to 6.0.0
  - 18072 : Fix issue as suggested
  - 18073 : Fix issue as suggested
  - 18074 : To be fixed as part of document Q/A

IG discussion topics

1. Define trigger event(s) in medication order entry workflow

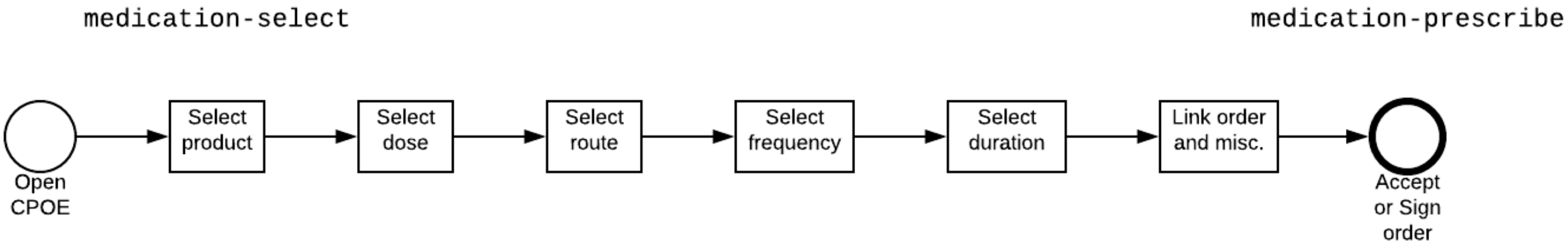
2. Passing resources (e.g., DetectedIssue) in card response

3. Card response covering core data elements for Minimum Information Model

IG discussion – trigger events

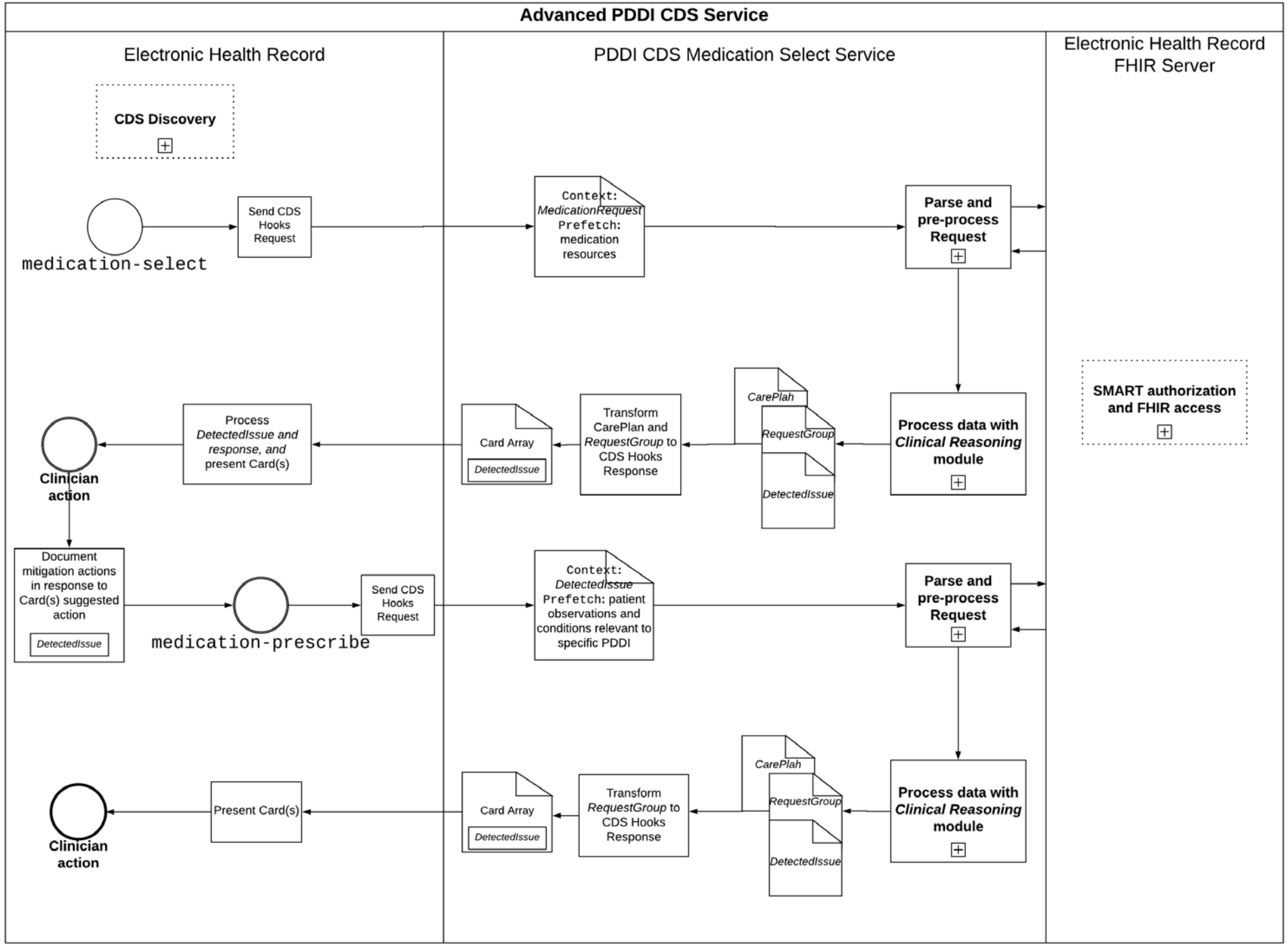
- Define trigger event(s) in medication order entry workflow
  - medication-prescribe (product selection vs. order accept/sign)
  - order-review (e.g., accept/sign for batch or individual order)
  - Multiple service coordination per task

Order entry workflow



IG discussion – DetectedIssue in card response

- Passing resources (e.g., DetectedIssue) in card response
  - Options to pass resources (object) without extension:
    1. card.source
    2. card.suggestion.action.resource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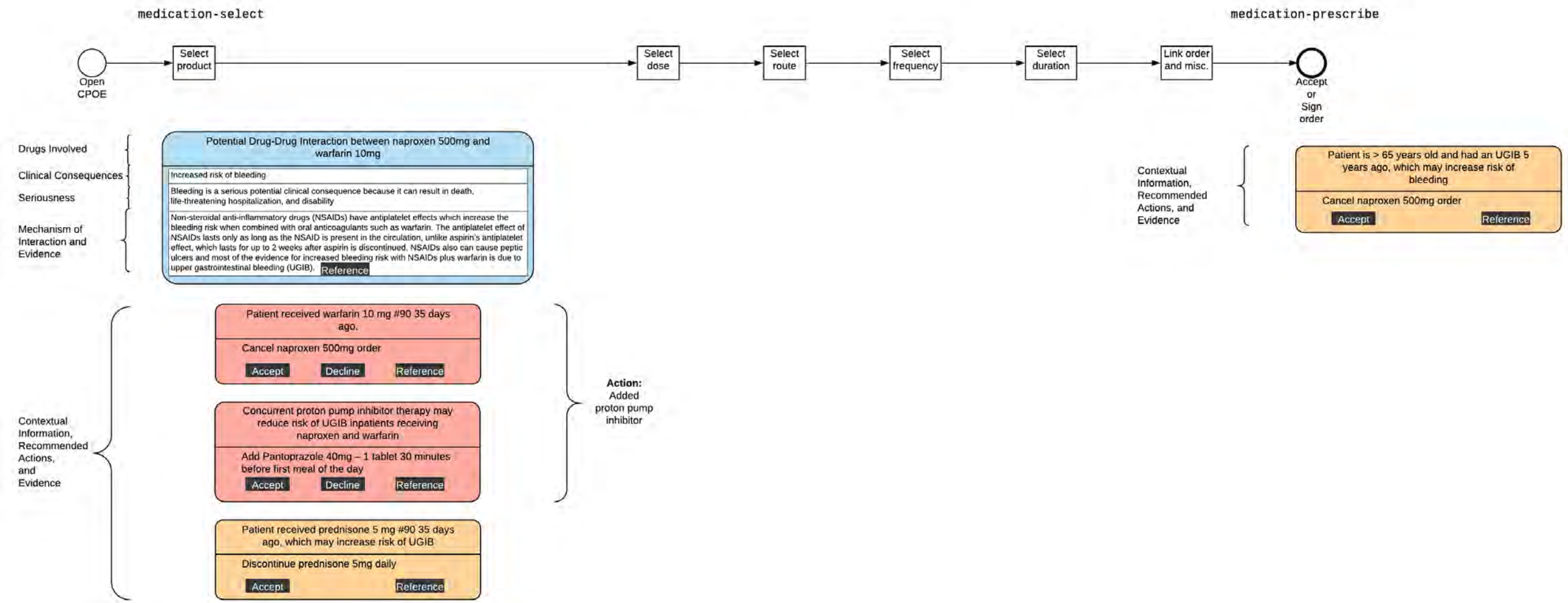
IG discussion – multiple card responses

- Card response covering core data elements for Minimum Information Model
  - `detail` element (markdown) as “catch-all” vs. extension
  - Multiple card response for more control on displaying content

Use case


medication-select
medication-prescribe
Open CPOE
Select product
Select dose
Select route
Select frequency
Select duration
Link order and misc.
Accept or Sign order
Drugs Involved
Clinical Consequences
Seriousness
Mechanism of Interaction and Evidence
Potential Drug-Drug Interaction between naproxen 500mg and warfarin 10mg
Increased risk of bleeding
Bleeding is a serious potential clinical consequence because it can result in death, life-threatening hospitalization, and disability
Non-steroidal anti-inflammatory drugs (NSAIDs) have antiplatelet effects which increase the bleeding risk when combined with oral anticoagulants such as warfarin. The antiplatelet effect of NSAIDs lasts only as long as the NSAID is present in the circulation, unlike aspirin's antiplatelet effect, which lasts for up to 2 weeks after aspirin is discontinued. NSAIDs also can cause peptic ulcers and most of the evidence for increased bleeding risk with NSAIDs plus warfarin is due to upper gastrointestinal bleeding (UGIB). Reference
Contextual Information, Recommended Actions, and Evidence
Patient is > 65 years old and had an UGIB 5 years ago, which may increase risk of bleeding
Cancel naproxen 500mg order
Accept
Reference
Contextual Information, Recommended Actions, and Evidence
Patient received warfarin 10 mg #90 35 days ago.
Cancel naproxen 500mg order
Accept
Decline
Reference
Concurrent proton pump inhibitor therapy may reduce risk of UGIB inpatients receiving naproxen and warfarin
Add Pantoprazole 40mg – 1 tablet 30 minutes before first meal of the day
Accept
Decline
Reference
Patient received prednisone 5 mg #90 35 days ago, which may increase risk of UGIB
Discontinue prednisone 5mg daily
Accept
Reference
Action: Added proton pump inhibitor

Minimum Information Model

1.4.1 W3C Effort

This implementation guide builds on the the W3C Community Group Note, *"A Minimum Representation of Potential Drug-Drug Interaction Knowledge and Evidence - Technical and User-centered Foundation."* This Note provides a technical and user-centered foundation for a PDDI minimum information model. The overarching goal of this project was to support effective PDDI CDS. The principal contributions of the Note include:

1. definitions for the model's core information items, examples of using these definitions to represent two PDDIs, and a set of additional PDDIs selected as case studies for future work using the information model;
2. clarification of model users, use cases, and specific information needs;
3. statement on the appropriate scope of knowledge representation for the information model;
4. potential applications of the minimum information model that could lead to improved patient safety.

This Community Group Note provides motivation and a detailed domain analysis for structuring PDDI knowledge with the minimum information model. The model elements include:

- **Clinical consequences**
- **Contextual information/modifying factors**
- **Drugs involved**
- **Evidence**
- **Frequency of exposure to the interacting drug pair**
- **Frequency of harm for persons who have been exposed to the interacting drug pair**
- **Mechanism of the interaction**
- **Recommended actions**
- **Seriousness rating**

Warfarin + NSAIDs (Draft 1)

Non-steroidal anti-inflammatory drugs (NSAIDs) have antiplatelet effects which increase the bleeding risk when combined with oral anticoagulants such as warfarin. The antiplatelet effect of NSAIDs lasts only as long as the NSAID is present in the circulation, unlike aspirin's antiplatelet effect, which lasts for up to 2 weeks after aspirin is discontinued. NSAIDs also can cause peptic ulcers and most of the evidence for increased bleeding risk with NSAIDs plus warfarin is due to upper gastrointestinal bleeding (UGIB).

Is NSAID topical diclofenac?	Yes	No					
Is there a suitable alternative to the NSAID in this patient?		Yes	No				
Is patient on proton pump inhibitor or misoprostol?			Yes	No			
Does the patient have one or more of the following risk factors: - history of UGIB or peptic ulcer - > 65 years old				Yes		No	
Is patient also taking: - systemic corticosteroids - aldosterone antagonist - high dose or multiple NSAIDs				Yes	No	Yes	No
Not likely to increase risk of UGIB	○[1]						
Use alternative to NSAID		○[2]					
Possible increased risk of UGIB or other bleeding			■[3]				
Substantially increased risk of UGIB or other bleeding				◆[4,5]			
Increased risk of UGIB or other bleeding					◆[4]	◆[5]	◆

○ = No special precautions. ■ = Assess risk and take action if necessary. ◆ = Use only if benefit outweighs risk

Card Attributes

Each **Card** is described by the following attributes.

Field	Optionality	Type	Description
`summary`	REQUIRED	*string*	One-sentence, <140 display to the user i
`detail`	OPTIONAL	*string*	Optional detailed in be represented in (urgent cards, the EH clicks a link like 'vie
`indicator`	REQUIRED	*string*	Urgency/importanc values, in order of increasing urgency, are: `info`, `warning`, `critical`. The EHR MAY use this field to help make UI display decisions such as sort order or coloring.
`source`	REQUIRED	*object*	Grouping structure for the **Source** of the information displayed on this card. The source should be the primary source of guidance for the decision support the card represents.

Suggestion

Each **Suggestion** is described by the following attributes.

Field	Optionality	Type	Description
`label`	REQUIRED	*string*	Human-readable label to display for this suggestion (e.g. the EHR might render this as the text on a button tied to this suggestion).
`uuid`	OPTIONAL	*string*	Unique identifier, used for auditing and logging suggestions.
`actions`	OPTIONAL	*array*	Array of objects, each defining a suggested action. Within a suggestion, all actions are logically AND'd together, such that a user selecting a suggestion selects all of the actions within it.