

# HL7 GDPR on FHIR

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# Agenda

- HL7 FHIR Security & Privacy artefacts
- Example
- HL7 GDPR Whitepaper

# HL7 - Security & Privacy

- HL7 defined several components to support implementation of security & privacy
  - CDA elements
  - FHIR components
    - Resources, Guidance, Vocabulary
  - General security guidance

# HL7 FHIR Security & Privacy

Structure

UML

XML











JSON

Turtle

R2 Diff

All

## Structure

Name	Flags	Card.	Type	Description & Constraints
 Consent	I		DomainResource	A healthcare consumer's policy choices to permits or denies reci purposes and periods of time <i>+ Either a Policy or PolicyRule</i>
 identifier	Σ	0..1	Identifier	Elements defined in Ancestors: <a href="#">id</a> , <a href="#">meta</a> , <a href="#">implicitRules</a> , <a href="#">language</a> Identifier for this record (external references)
 status	?! Σ	1..1	code	draft   proposed   active   rejected   inactive   entered-in-error <a href="#">ConsentState</a> (Required)
 category	Σ	0..*	CodeableConcept	Classification of the consent statement - for indexing/retrieval <a href="#">Consent Category Codes</a> (Example)
 patient	Σ	1..1	Reference(Patient)	Who the consent applies to
 period	Σ	0..1	Period	Period that this consent applies
 dateTime	Σ	0..1	dateTime	When this Consent was created or indexed
 consentingParty	Σ	0..*	Reference(Organization   Patient   Practitioner   RelatedPerson)	Who is agreeing to the policy and exceptions
 actor	Σ	0..*	BackboneElement	Who what controlled by this consent (or group, by role)
 role		1..1	CodeableConcept	How the actor is involved <a href="#">SecurityRoleType</a> (Extensible)

# HL7 FHIR Security & Privacy

## ■ Resources

### – Consent

- Express consent regarding healthcare
- Currently Privacy consent directive is well defined: agreement to collect, access, use or disclose (share) information
- Enables capturing, storing, transmitting simply to complex privacy policies
- <http://hl7.org/implement/standards/fhir/consent.html>

### – Provenance

- describes entities and processes involved in producing and delivering or otherwise influencing a resource.
- Provides a critical foundation for assessing authenticity, enabling trust, and allowing reproducibility
- based on the W3C Provenance specification
- <http://hl7.org/implement/standards/fhir/provenance.html>

# HL7 FHIR Security & Privacy

## ■ Resources

### – Audit Event

- record of an event made for purposes of maintaining a security log
- based on the IHE-ATNA Audit record definitions, originally from RFC 3881 , and now managed by DICOM
- actors - such as applications, processes, and services - involved in an auditable event should record an AuditEvent
- <http://hl7.org/implement/standards/fhir/auditevent.html>

# HL7 FHIR Security & Privacy

- Implementation Guidance & Principles
  - Security Labels
    - concept attached to a resource or bundle that provides specific security metadata about the information
    - Context of Use
      - Purpose Of Use
    - Data Sensitivity
      - Confidentiality codes
    - Control Flow
    - <http://hl7.org/implement/standards/fhir/security-labels.html>

# HL7 FHIR Security & Privacy

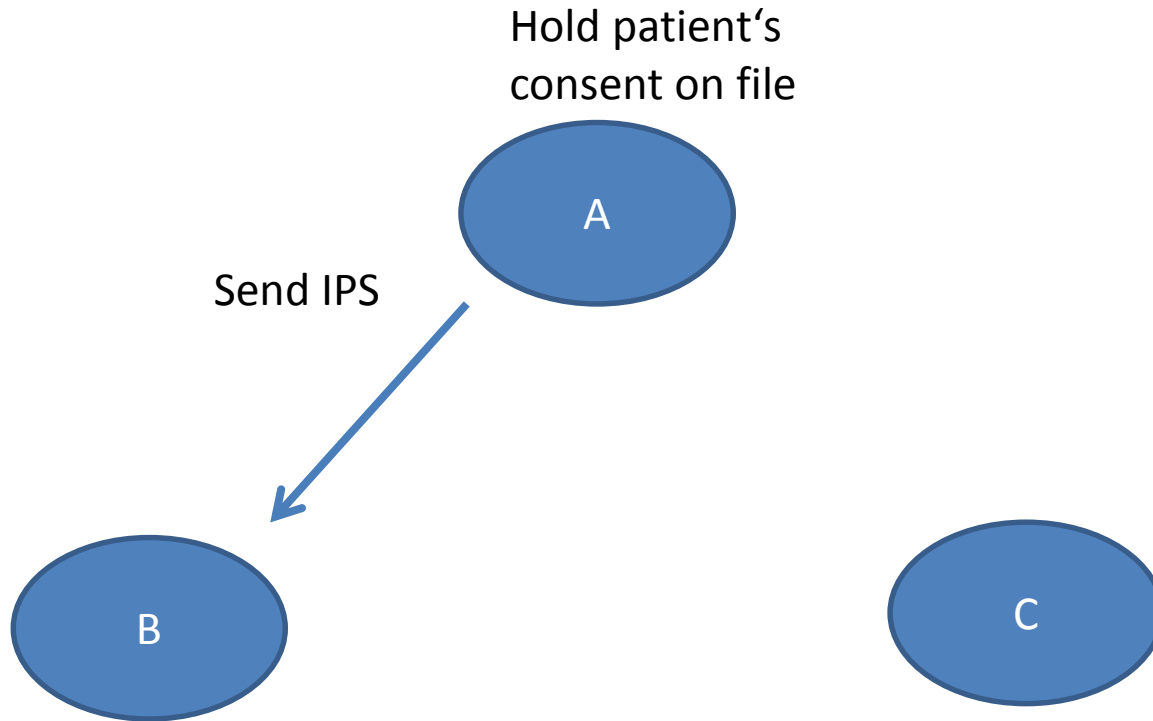
- Implementation Guidance & Principles
  - Security Principles
    - Secure Communication
    - Authentication
    - Authorization / Access control
    - ...
    - <http://hl7.org/implement/standards/fhir/security.html>



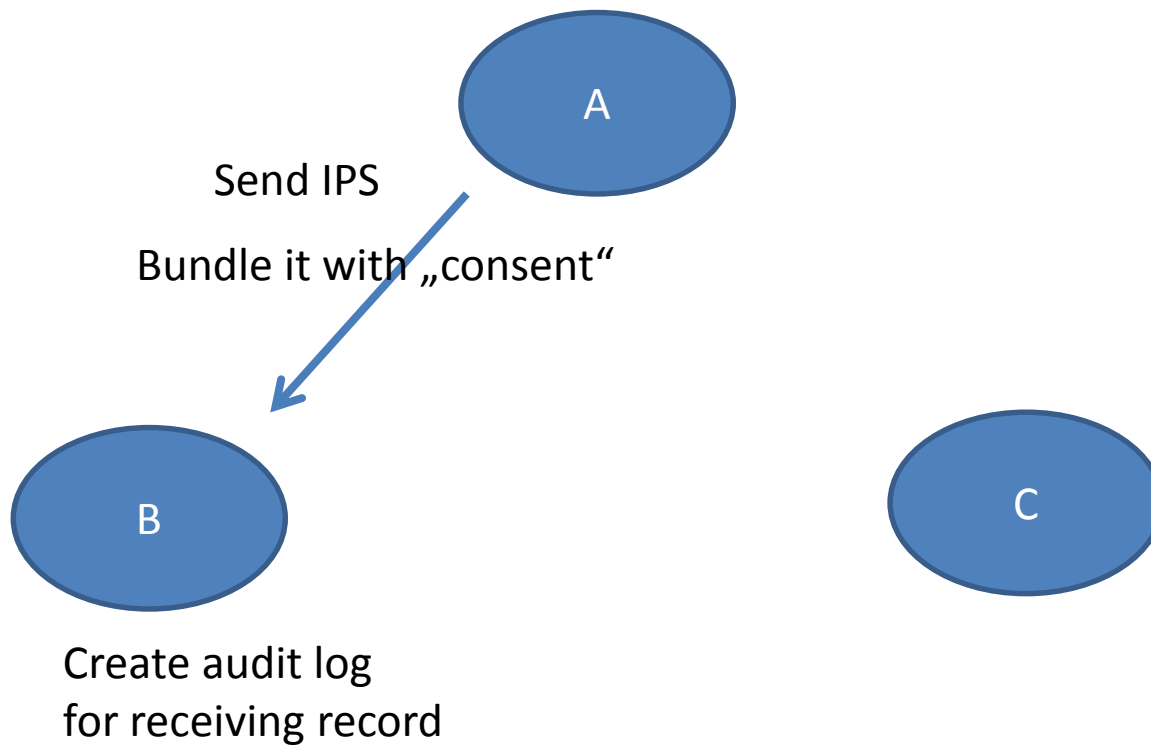
# HL7 FHIR Security & Privacy

- Vocabulary
  - Purpose Of Use
    - Currently adopted according to GDPR art. 6 & 9
  - confidentiality classification
  - InformationSensitivityPolicy
  - ...

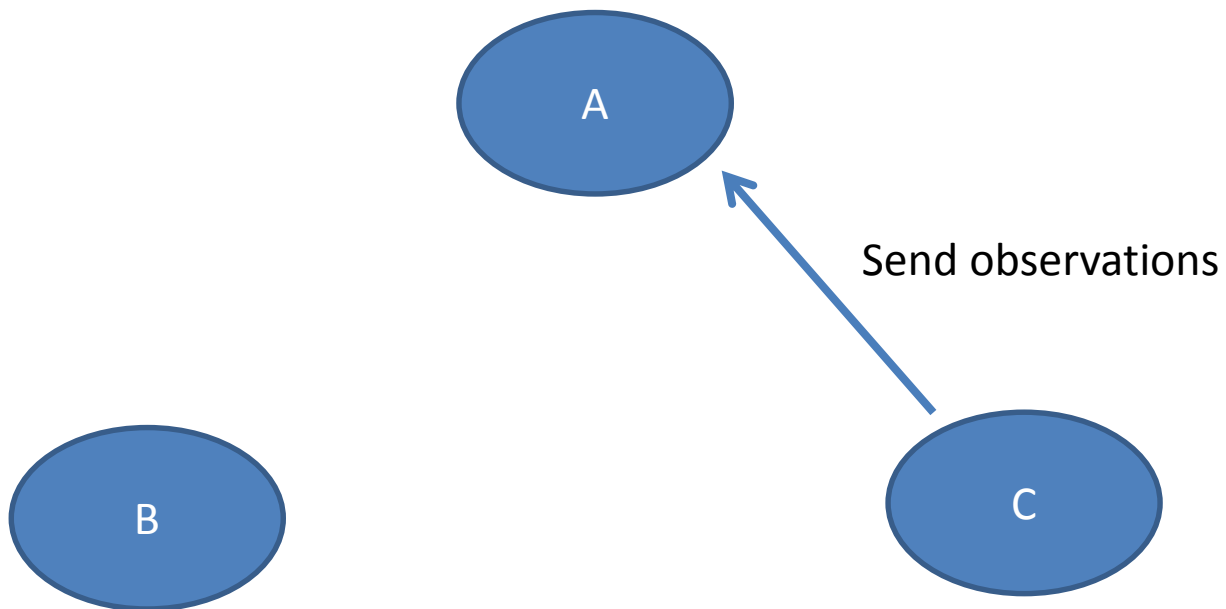
# Example



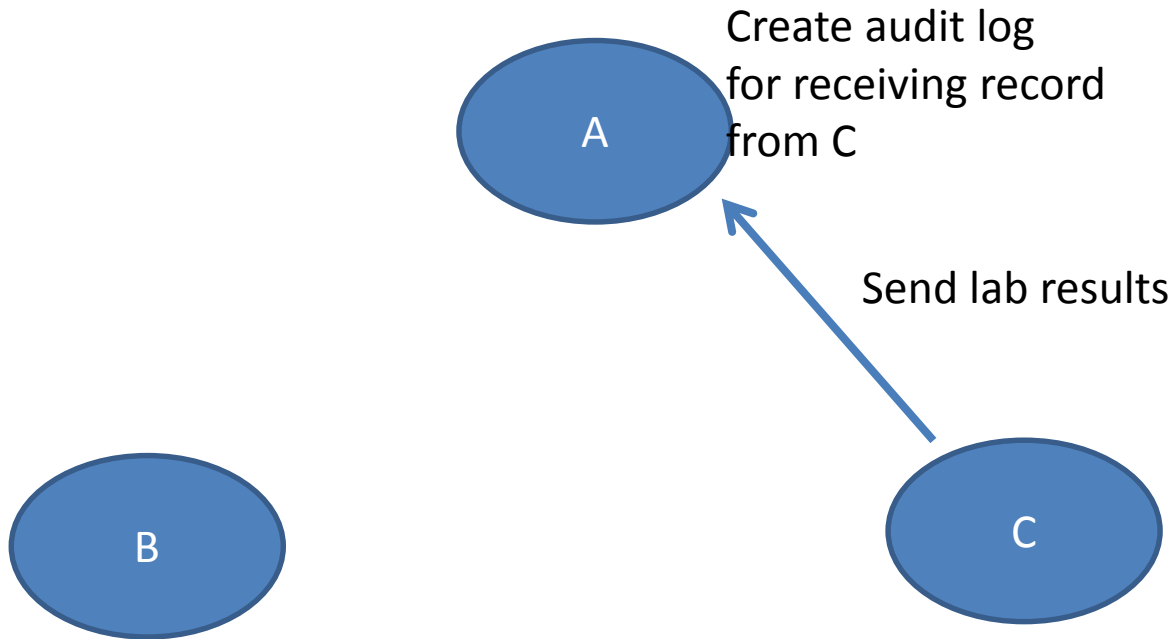
# Example



# Example

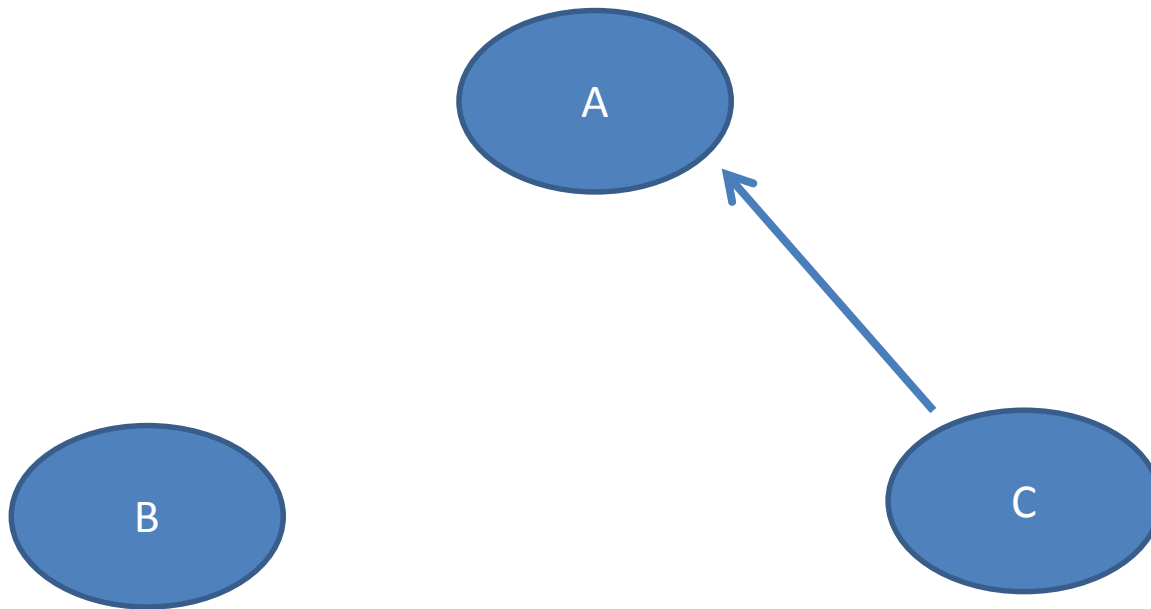


# Example



# Example

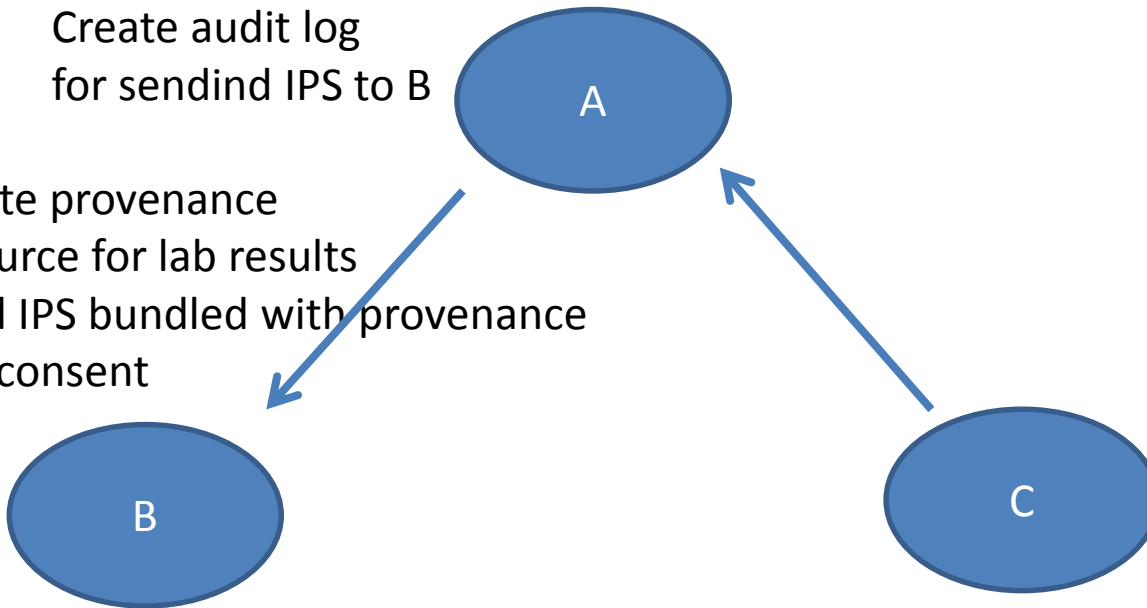
Tag data with  
sensitivity class



# Example

Create audit log  
for sending IPS to B

- Create provenance resource for lab results
- Send IPS bundled with provenance and consent



Create audit log  
for receiving record  
from A

# HL7 GDPR Whitepaper

- Goal: Provide guidance how HL7 FHIR components support implementation of GDPR requirements
- General principles
  - Focussed on FHIR / technical level
  - No specific policies
  - No legal assumptions
- Work in progress
  - <https://confluence.hl7.org/display/SEC/FHIR+++GDPR>
  - Weekly ConfCall



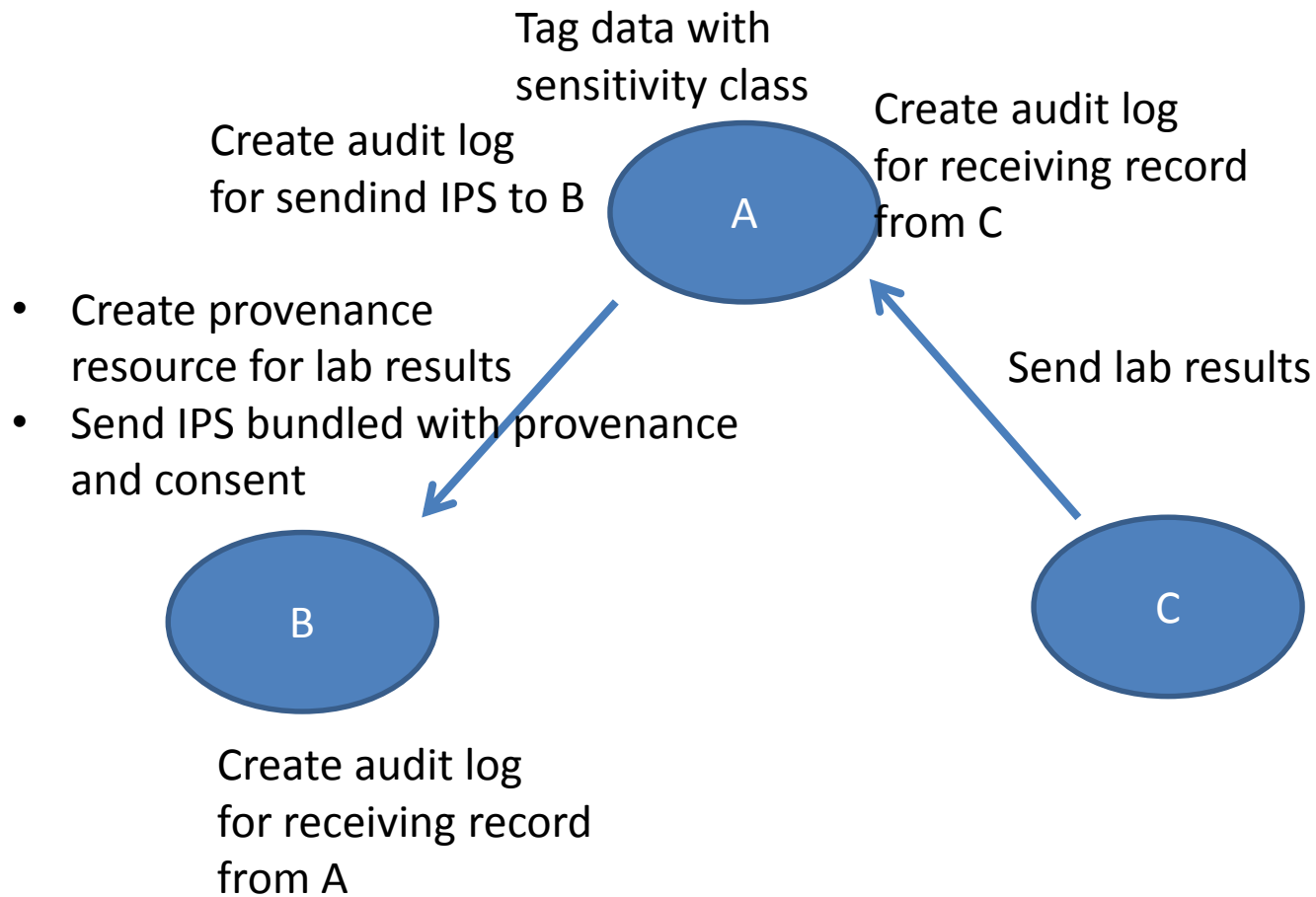
# HL7 GDPR Whitepaper

- Requirement for explicit consent ...
  - The consent resource might be used to hold specific consent on file or to send information about given consent along with healthcare information.
- Requirement for transparency ...
  - means a controller needs to keep track of the processing of personal data and provide information. To store information about data sources either AuditEvent or Provenance can be used ...

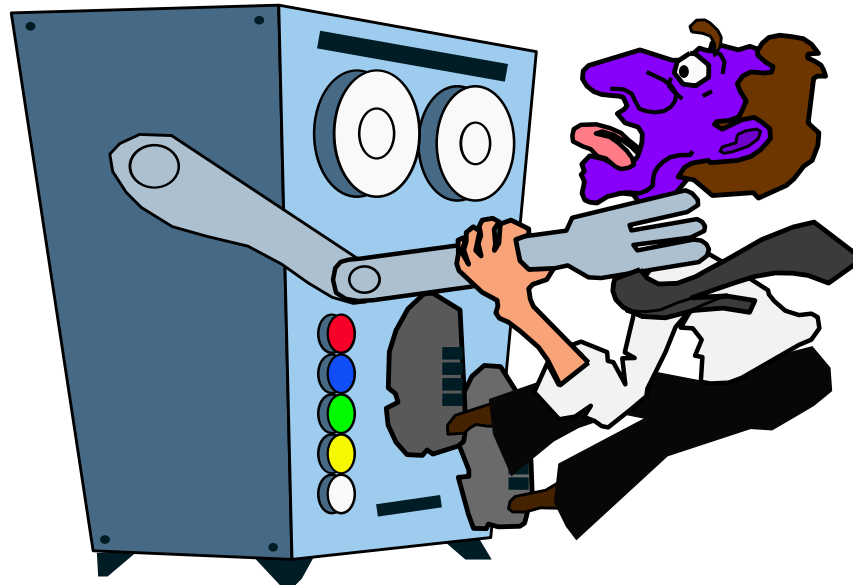
# HL7 GDPR Whitepaper

- Work progress
  - Mapping Requirements of GDPR to existing components (e.g. resources, security labels, vocab, ...)
  - Identify gaps
  - Provide „whitepaper“
  - Provide simple examples
  - Propose future work items to be done by HL7
- Examples
  - It's planned to include examples – handling IPS might be a complex one
  - but probably already bound to specific policies?

# Example



# Thanks for your attention



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