DATA SHARING FRAMEWORK

Fostering Research

Real World Data Sharing and Process Orchestration with FHIR and BPMN

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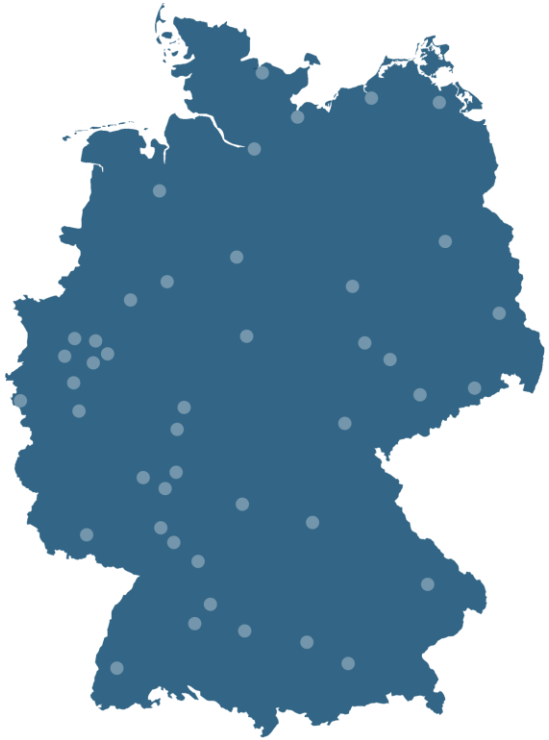
Motivation

DATA SHARING FRAMEWORK

- Enhanced research collaboration
- Standardized data access and usage
- Interoperable solution

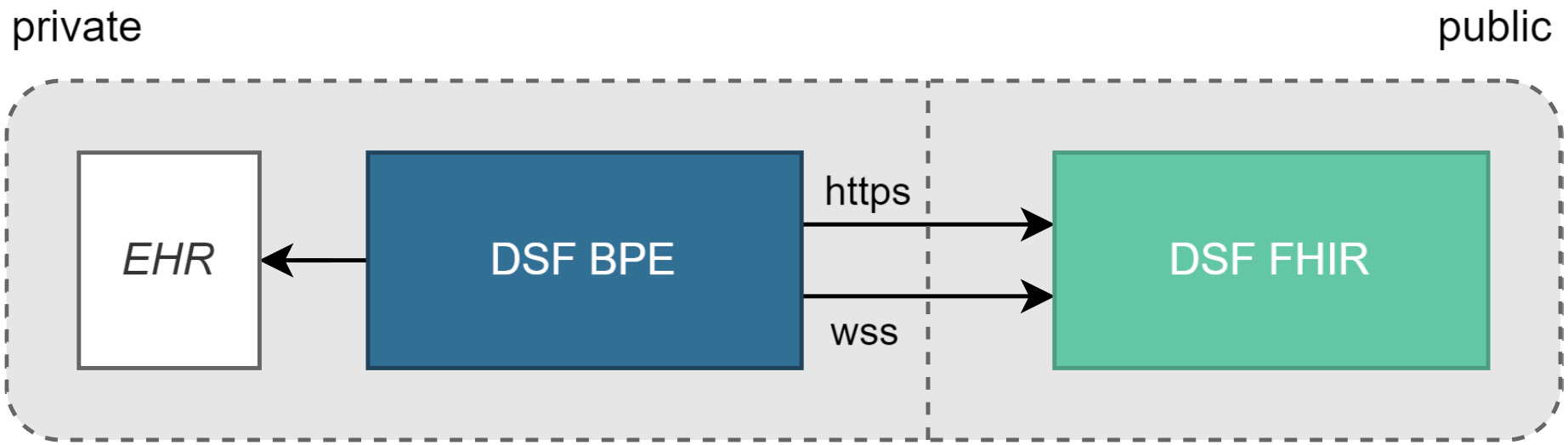


- Data discovery with feasibility queries
- Coordination of data requests and approvals
- Data transport, consolidation, pseudonymization and distribution
- Distributed data analysis

Data Sharing Framework

Public: FHIR Server “Mail Box”

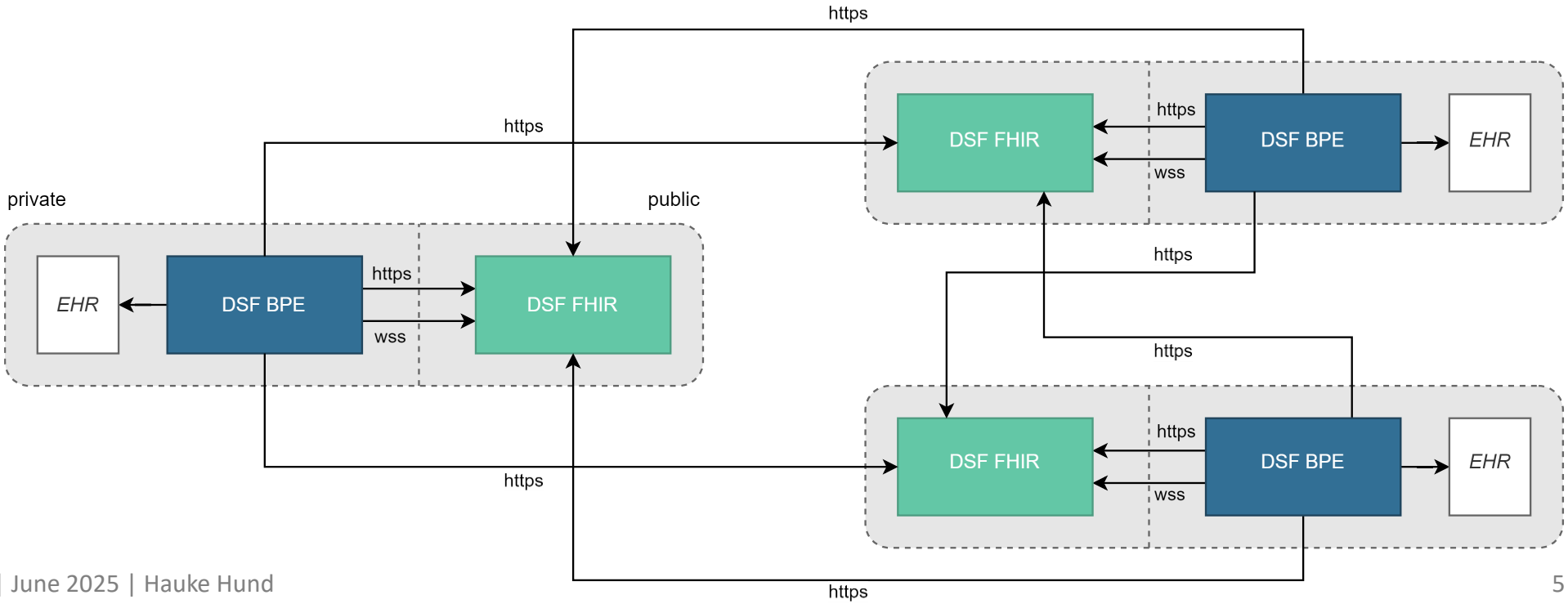
Private: Business Process Engine



Data Sharing Framework

DATA SHARING FRAMEWORK

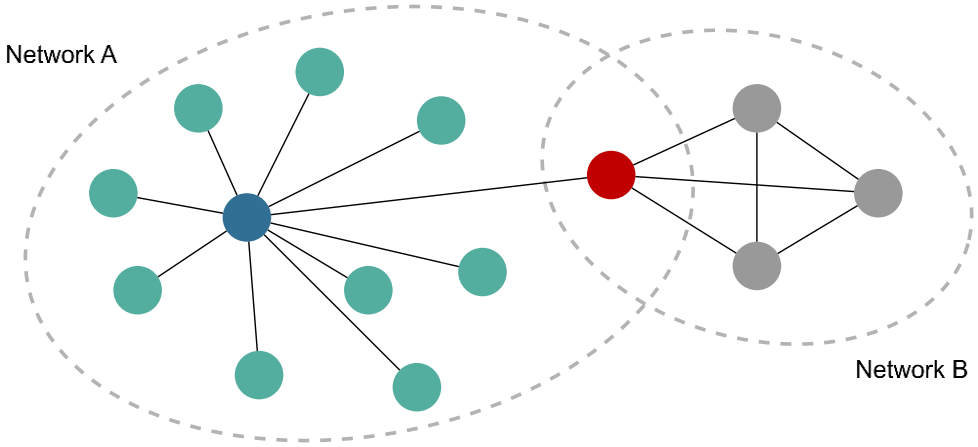
A distributed business process engine to coordinate and exchange medical data in healthcare research and delivery



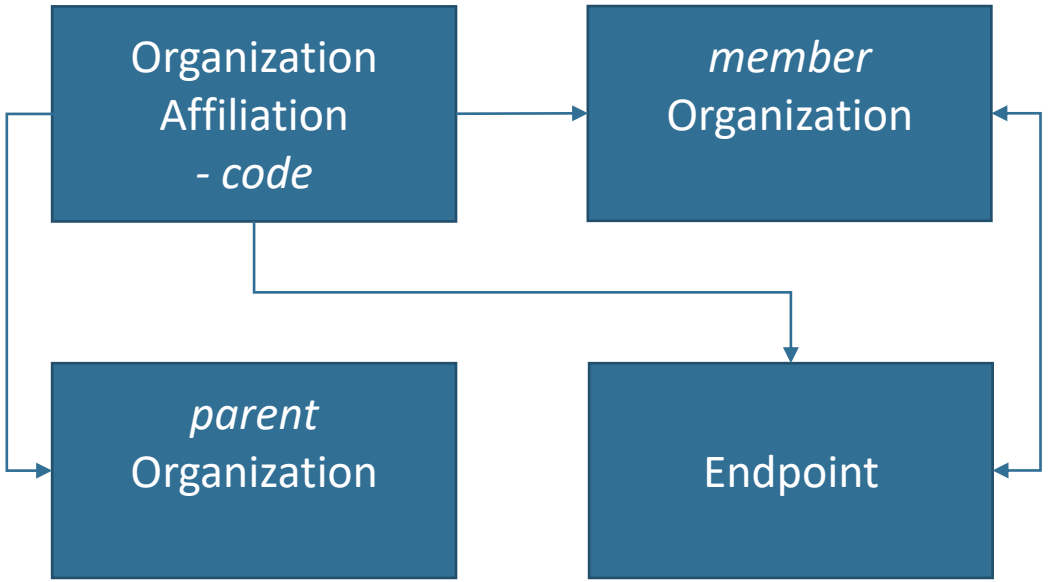
Research Networks by Configuration

DATA SHARING FRAMEWORK

One DSF instance can operate in multiple research / healthcare delivery networks



Allow-List configures roles in network



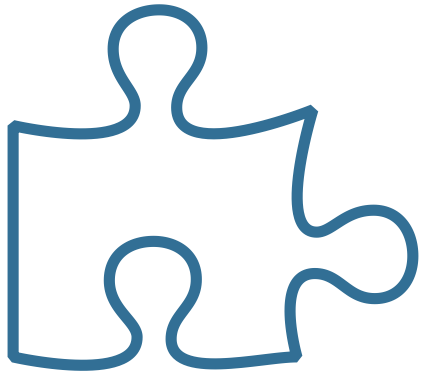
Process Plugins

DATA SHARING FRAMEWORK

- Use case specific data structures and logic
- A process plugins is an archive with

  BPMN 2.0 models
  FHIR R4 resources
  Java Code

- Deployed in the DSF BPE as a Jar file
  - Web Application Style Class Loading
  - Same process, multiple versions



BPMN and FHIR

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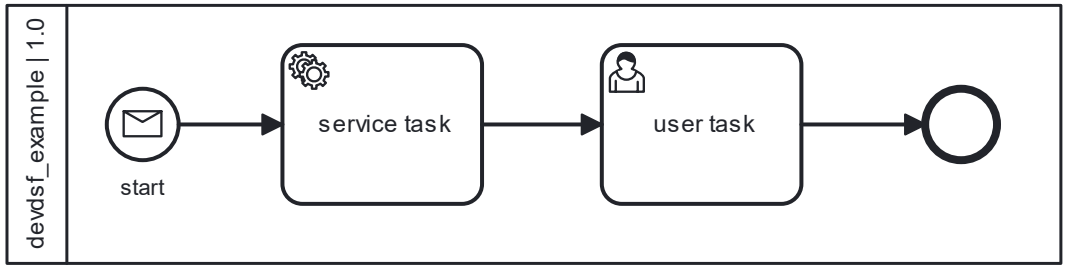
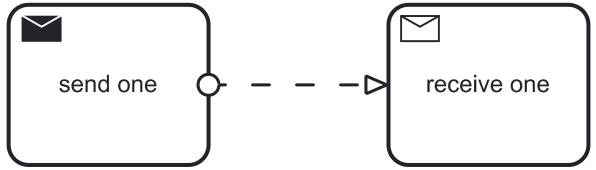
Process



Message Send / Receive Tasks



Message Events

```
Alias: $pa = http://dsf.dev/fhir/
                              CodeSystem/process-authorization

Instance: 8ce64ff9-bea6-4674-a305-0f8c7591fe23
InstanceOf: ActivityDefinition
Usage: #example
* extension.url = "http://dsf.dev/fhir/
      StructureDefinition/extension-process-authorization"
* extension.extension[0].url = "message-name"
* extension.extension[0].valueString = "start"
* extension.extension[1].url = "task-profile"
* extension.extension[1].valueCanonical = "http://dsf.dev/
                        fhir/StructureDefinition/example|1.0"
* extension.extension[2].url = "requester"
* extension.extension[2].valueCoding = $pa#REMOTE_ALL
* extension.extension[3].url = "recipient"
* extension.extension[3].valueCoding = $pa#LOCAL_ALL

* url = "http://dsf.dev/bpe/Process/example"
* version = "1.0"          /* version managed by DSF BPE */
* status = #active         /* status managed by DSF BPE */
* date = "2025-06-06"        /* date managed by DSF BPE */
* kind = #Task
```

BPMN: Encrypted Data Transfer

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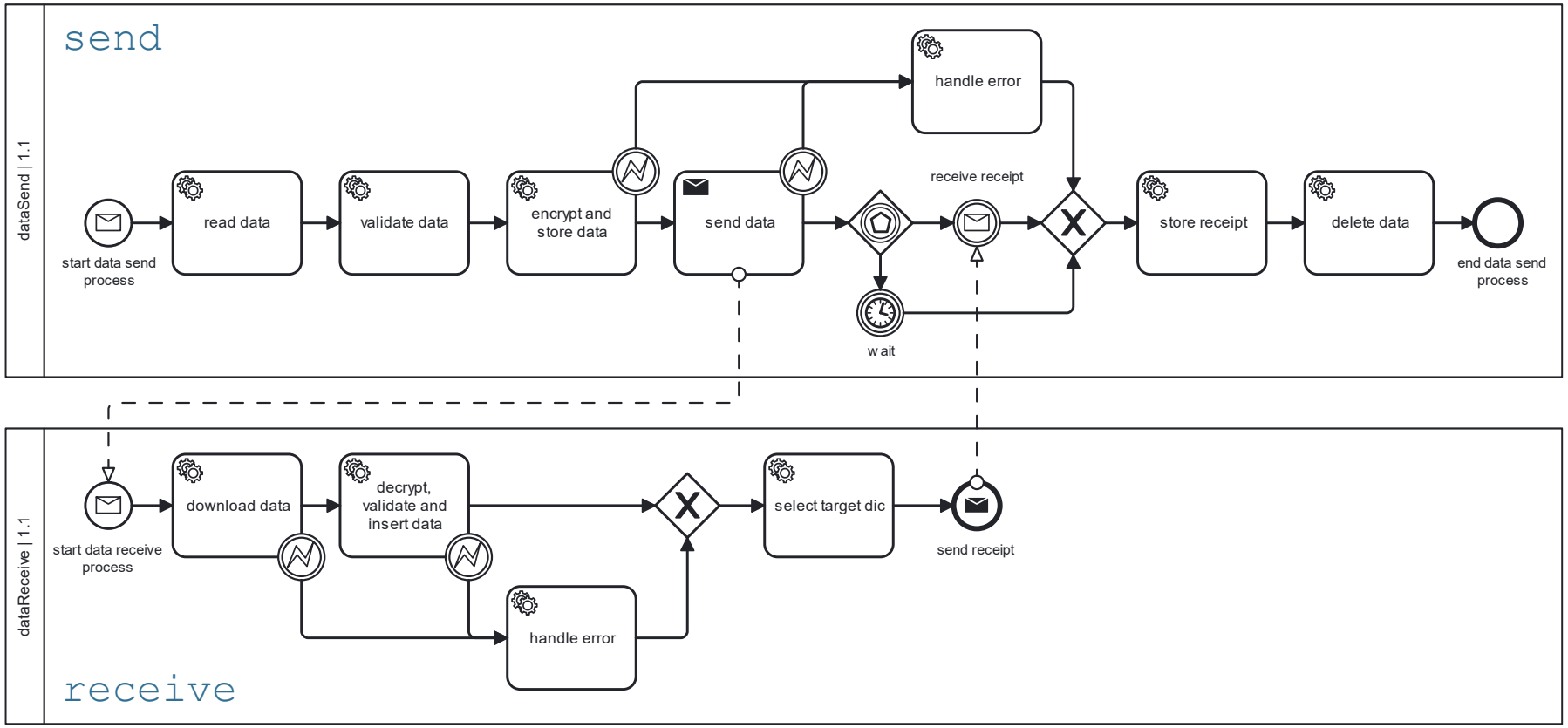

- Read from EHR, validate, encrypt, store
- Send trigger

- Download, decrypt, validate, store
- Send receipt

https://github.com/medizininformatik-initiative/mii-process-data-transfer

FHIR: Task Resource (FSH)

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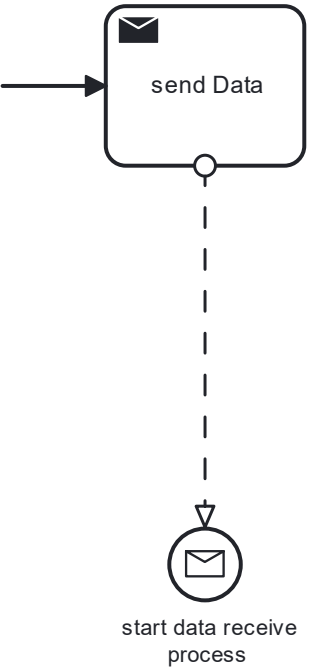



```
Alias: $bpmn-message = http://dsf.dev/fhir/CodeSystem/bpmn-message
Alias: $data-transfer = http://medizininformatik-initiative.de/fhir/CodeSystem/data-transfer

Instance: aca4663c-851e-4c33-950b-5ddb40f19afa
InstanceOf: Task
Usage: #example
* meta.profile = "http://medizininformatik-initiative.de/fhir/StructureDefinition/task-data-send|1.1"
* instantiatesCanonical = "http://medizininformatik-initiative.de/bpe/Process/dataReceive|1.1"
* status = #requested
* requester.identifier.system = "http://dsf.dev/sid/organization-identifier"
* requester.identifier.value = "sender.org"
* restriction.recipient.identifier.system = "http://dsf.dev/sid/organization-identifier"
* restriction.recipient.identifier.value = "receiver.org"
* input[0].type = $bpmn-message#message-name
* input[0].valueString = "dataSend"

* input[1].type = $data-transfer#document-reference-location
* input[1].valueReference = Reference(https://dsf.sender.org/fhir/DocumentReference/
                                     ad900831-9872-47e3-ad07-62ca65a067a1)
* input[2].type = $data-transfer#project-identifier
* input[2].valueIdentifier.system = "http://medizininformatik-initiative.de/sid/project-identifier"
* input[2].valueIdentifier.value = "a-project-identifier"
```

https://github.com/medizininformatik-initiative/mii-process-data-transfer

Java: Asymmetric Encryption with ECDH KEM

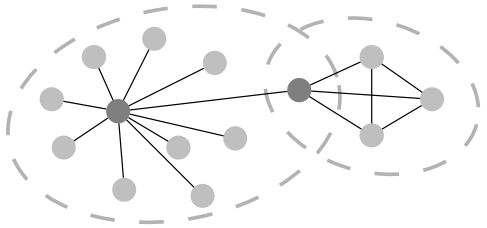
DATA SHARING FRAMEWORK

```java
public class DemoCryptoService implements dev.dsf.bpe.v2.activity.ServiceTask
{
	@Override
	public void execute(ProcessPluginApi api, Variables variables) throws ErrorBoundaryEvent, Exception
	{
		KeyPair x448KeyPair = api.getCryptoService().createKeyPairGeneratorX448AndInitialize().generateKeyPair();
		byte[] encrypted = send(api.getCryptoService(), x448KeyPair.getPublic());
		receive(api.getCryptoService(), x448KeyPair.getPrivate(), encrypted);
	}

	private byte[] send(CryptoService cryptoService, PublicKey publicKey) throws Exception
	{
		byte[] encrypted = cryptoService.createEcDhKem().encrypt("sensitive-data".getBytes(StandardCharsets.UTF_8), publicKey);
		// store encrypted data in local DSF FHIR server, create download trigger task in remote DSF FHIR server
		return encrypted; // encapsulation, iv, encrypted data
	}

	private void receive(CryptoService cryptoService, PrivateKey privateKey, byte[] encrypted) throws Exception
	{
		// download encrypted data from remote DSF FHIR server
		byte[] decrypted = cryptoService.createEcDhKem().decrypt(encrypted, privateKey);
		assert "sensitive-data".equals(new String(decrypted, StandardCharsets.UTF_8));
	}
}
```

Summary

DATA SHARING FRAMEWORK

Extendable with independent use case specific process plugins



Configurable to connect projects, organizations and research networks

Standardized using HL7 FHIR R4 for communication and data storage as well as BPMN 2.0 for visualization and logic

Deployed with 50 installations in Germany

Additional Information and Contact

DATA SHARING FRAMEWORK

dsf.dev

- FHIR Implementation Guide
- Plugin API JavaDoc

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