Norwegian Health Consortium

siva

Health Data Standards

This service package offers access to technology experts with extensive experience in developing standards-based technology strategies for healthcare companies. A structured approach will help you design your solution around existing and emerging standards in health and fitness data.

This package will ensure that you leverage off-the-shelf standards-based solutions, conform to national requirements and recommendations

Investment: NOK 29 750 (value NOK 85,000, eks. VAT)

Delivered by Validé and our Norwegian Smart Care Lab in collaboration with Egde Consulting, send your request to karoline@valide.no

Aleap for health startups

norinnova TECHNOLOGY TRANSFER

NTNU

SINTEF

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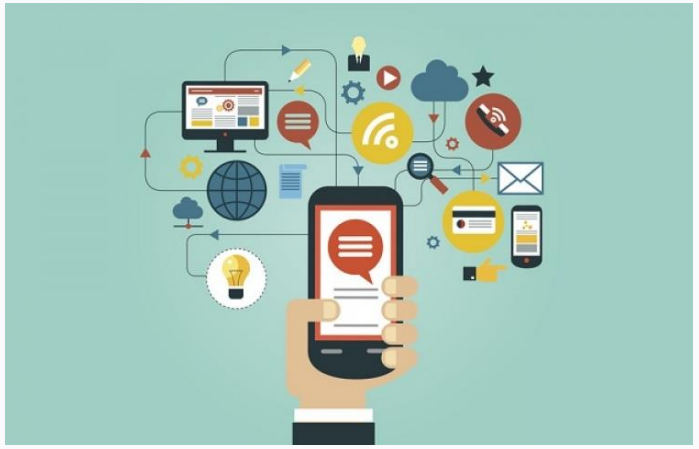
Why Health Data Standards

Data standards, security and privacy requirements, and advanced health IT systems are critical to achieve full healthcare interoperability. This service package will get your company headed in the right direction with practical standards and best practices for future interoperability within healthcare IT systems. Code of conduct will help to create a common understanding of the threats, requirements and offers an approach of how to deal with information security in businesses developing medical devices or services. Also, this focus area will help the company to implement the Codes requirements for the processing of health and personal data in medical equipment with associated system solutions and applications in a practical way.



<u>The benefits:</u>

- Faster time-to-market/scale nationally and internationally;
- Supported by off-the-shelf and open source solutions;
- Compliant APIs;
- Rapid interoperability with other compliant systems and devices;
- Improved technical due-diligence for customers and investors;
- Recommended or required by international health services.
- Visualised desired future state of the Company's Information Security Structure
- Overview of the guideline and security requirements of the Code of Conduct or other desired Information Security controls (ISO/IEC 27002)

The output will rely upon which focus area the company choose, ***Interoperability*** *or* ***Code of conduct****.*

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Tailored service based on your needs

Choose among two different focus areas based on your needs:

1. Interoperability: maximise your product interoperability with patient journals and other national and international health solutions.

2. Code of conduct: information security and data protection. The norm for information security and privacy in the health and care service (the norm) is an agreed set of requirements for information security based on legislation.

Disclaimer: You can choose one focus area per package.

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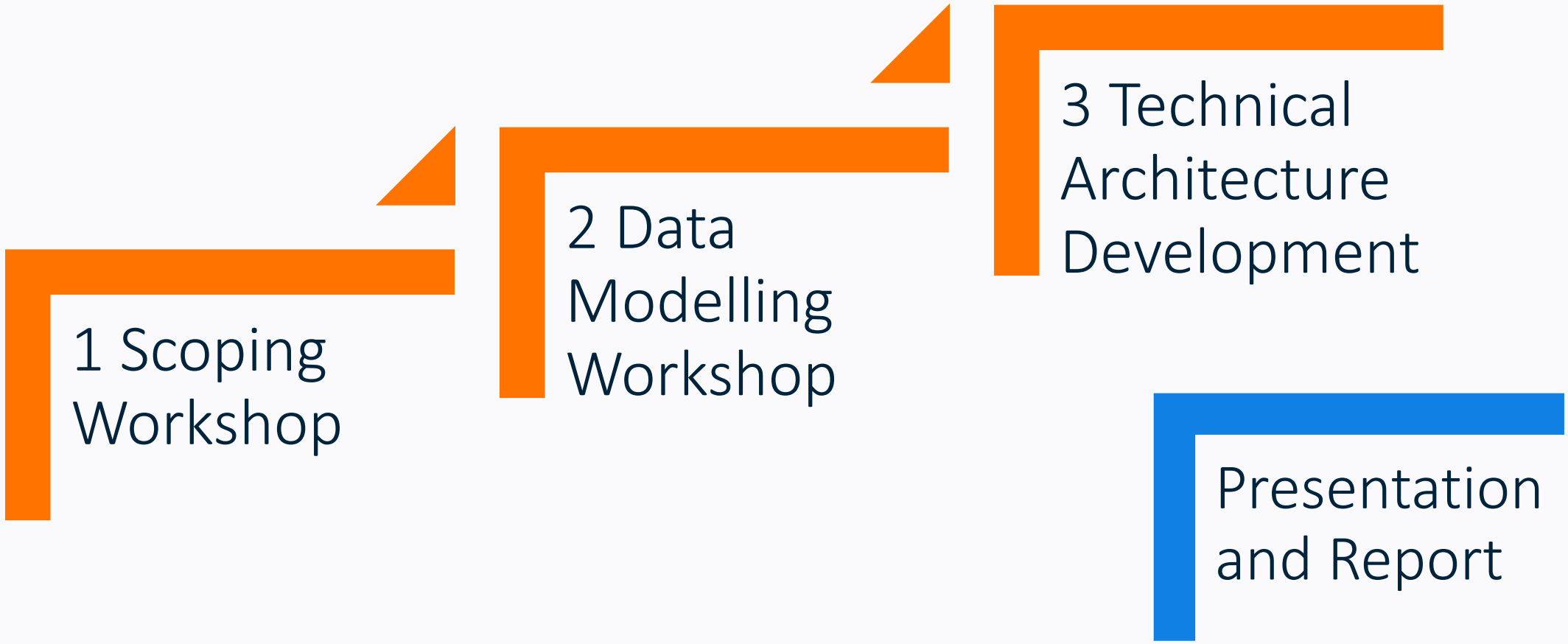
Focus area 1: Interoperability



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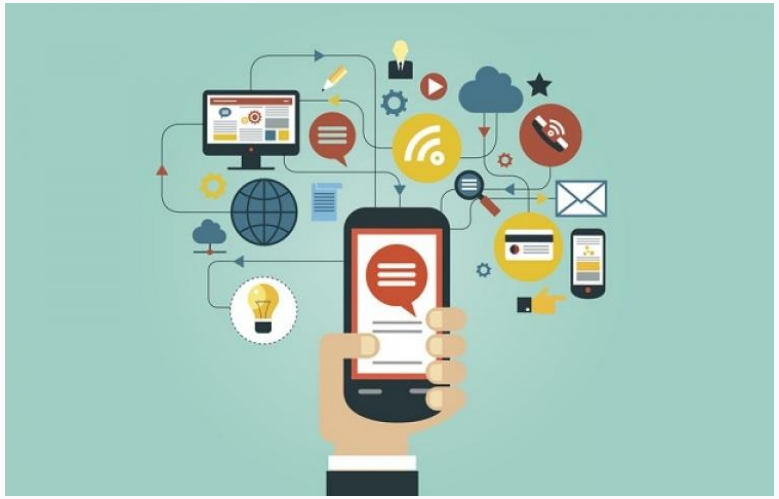
Intropерability

Data standards, security and privacy requirements, and advanced health IT systems are critical to achieve full healthcare interoperability. This service package will get your company headed in the right direction with practical standards and best practices for future interoperability within healthcare IT systems.

The benefits:

- Faster time-to-market/scale nationally and internationally;
- Supported by off-the-shelf and open source solutions;
- Compliant APIs;
- Rapid interoperability with other compliant systems and devices;
- Improved technical due-diligence for customers and investors;
- Recommended or required by international health services.



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1. Scoping Workshop

A workshop between the company and the subcontractor to define an initial overview of the product description focusing on its data requirements and data flows for the Device or Service.

The company will be expected to share any relevant background information about their technology and market understanding prior to the workshop. 1-2 Hours

During the workshop it is expected that the company will present their product, technology and research objectives, key milestones and delivery dates that need to be met. They should also have a draft of the Product Roadmap. Egde will facilitate a discussion on the potential standards, requirements and integration potential for a medical device or service. 3-4 Hours

Outcome (Interoperability) for this step will give the Company recommendations in the final report for:

- Which technology standards the company should adopt e.g. the practical use of FHIR;
- Adoption of secure connectivity approaches;
- Coding standards needed for interoperability;
- Security standards and recommendations required in the solution.

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Step 2: Data Modelling Workshop

This workshop is a collaboration between the Company and Egde to define the data modelling standards required.

With the output from this workshop the Company and Egde will have:

- Identified the health and supporting data resources and structures to be used in the project;
- Identified which national and international profiles should be adopted for interoperability in the prioritised markets.

This is important input for the solution developers when they come to use of the data resources and develop a standards-based implementation.

Company input/ workload: technical and product input to a workshop of 2 to 3 hours plus follow-up questions.

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Step 3: Architecture development

This step consists of collaboration between the company and Egde to define a outline data services architecture for the product or service.

With the output of this step the Company will have a draft architectural design (MVP level) for a test and proof-of-concept server that is:

- A standards compliant data server based on cloud services where appropriate;
- A technical architecture description for data flow and interoperability components;
- A draft implementation guide;
- An API design that can be used by internal components and external parties to interact with the server;
- A description of the technical security framework required by the service.

Company input: answer questions via email and online meetings as required. Workload:

Outcome: will be presented to the company in a c.1 hour meeting and as a PowerPoint presentation.

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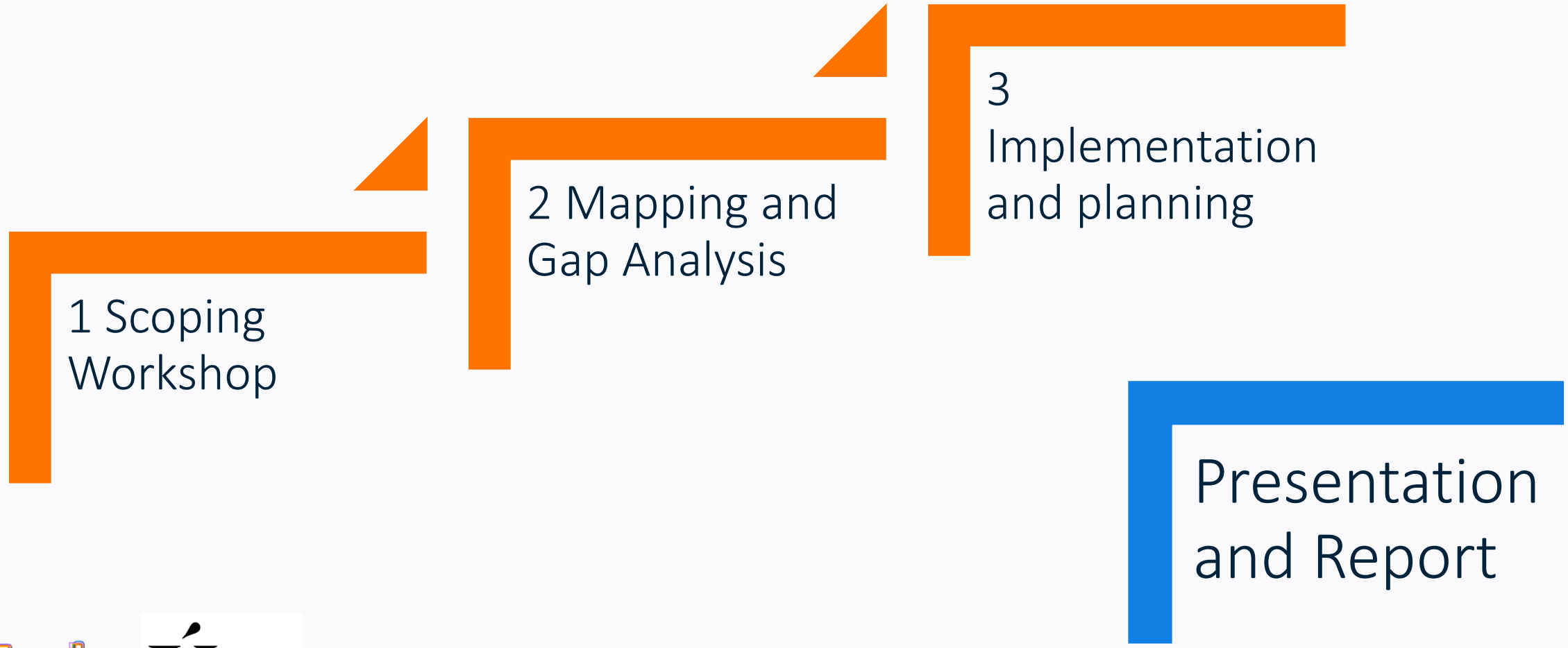
Focus area 2: Code of conduct



Code of Conduct – Information Security and Data Protection

The norm for information security and privacy in the health and care service (the norm) is an agreed set of requirements for information security based on legislation.

A structured approach to implementation of the requirements will help both your organization and your device/service achieve the security level required for bringing your product to market.

This service package offers access to Information Security experts with extensive experience with the Code of Conduct for information Security in the Norwegian Healthcare Sector.

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Code of Conduct

The Code of Conduct for information security and data protection in the Norwegian healthcare industry is a holistic approach to an information security policy for organizations within the sector.

The Code of Conduct is rooted in the ISO/IEC 27000 family but offers a set of requirement directly targeted to organizations dealing with health data. The Code ensures a secure interoperability for all organizations that comply with the regulations set in the Code.

This service package will help to create a common understanding of the threats, requirements and offers an approach of how to deal with information security in businesses developing medical devices or services.

The service package will help the Company to implement the Codes requirements for the processing of health and personal data in medical equipment with associated system solutions and applications in a practical way.

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Step 1 – Scoping workshop

A workshop between the company and the subcontractor to define an initial overview of the scope of organizational requirements, data requirements and data flows for the Device or Service.

The company will be expected to share any relevant background information about their technology and organizational context. **Workload: 1-2 hours.**

During the workshop it is expected that the company will present their organizational structure, product, technology and objectives, as well as key milestones and delivery dates that need to be met. Egde will facilitate a presentation of the main content of the Code of Conduct, and a discussion on the potential impact the implementation of the Code may have. **Workload: 3-4 hours.**

Outcome for this step will give the Company

- Visualised desired future state of the Company's Information Security Structure
- Overview of the guideline and security requirements of the Code of Conduct or other desired Information Security controls (ISO/IEC 27002)
- Overview of the requirements in the Code of Conduct not applicable for the Company

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Step 2 – Mapping and Gap Analysis Workshop

This workshop is a collaboration between the Company and Egde to to determine what steps need to be taken in order to move from its current state to the desired, future state.

In the workshop, all applicable requirements will be reviewed, and it will be determined if the Company complies to the measure, or if additional organizational or technical measures need to be implemented.

With the output from this workshop the Company and Egde will have:

- An overall picture of the challenge areas.
- A list of high-level measures prepared with priorities and a timetable for when to solve the challenges.

Company input/ workload: technical and product input to a workshop of 6 hours plus follow-up questions.

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Step 3 - Implementation

This step consists of collaboration between the company and Egde to define the course of action of when and how to close all gaps and associated risks.

With the output of this step the Company will have a Risk Management file, containing:

- A documented Security Review/Gap analysis;
- Gaps are reported as information security risks (direct input to risk assessment);
- Risk Register for tracking mitigating all associated risks;
- A System Security Plan, including detailed measure to be implemented to comply with the Code of Conduct;
- A Organizational Security plan to comply with the Code of Conduct or other applicable Information Security Standard

***Company input**:* answer questions via email and online meetings as required. **Workload: 2-4 hours.**

***Outcome**:* will be presented to the company in a c.1 hour meeting and as a PowerPoint presentation.

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Delivered by Validé - Practicalities

- Target group: Members of Siva supported incubators and business gardens
- Preliminary work facilitated by Valide, with inputs from company and subcontractor: Identify the focus area of the workshops, identify the companies needs, set expectations, plan and pre-pare the three steps of digital workshops that will enable you to leverage off-the-shelf standards-based solutions, conform to national requirements and recommendations and maximise your product interoperability with patient journals and other national and international health solutions.
- This package does not include legal advice.
- Governance: All participants must sign an NDA
- Investment: 29 750 NOK

** The value of this package is NOK 85 000. It includes three digital workshops and prelimenary work executed by Validé co. Norwegian Smart Care Lab. All prices are excluding VAT*

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