Lab module for **navify**® Integrator

Publication version 1.1
Installation Guide

Publication information

Publication version	Lab module for navify® Integrator software version	Revision date	Change description
1.0	2.7 and above	June 2024	First edition
1.1	2.7 and above	August 2024	• Updated the connectivity requirements Unified Gateway connectivity requirements (13) Virtual machine connectivity requirements (15) • Minor updates for correctness

Revision history

Edition notice

This publication is intended for users of Lab module for **navify**® Integrator.

We have made every effort to make sure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities. A new version of this publication is then created.

Where to find information

The **Installation Guide** describes the following:

- System requirements and installation information for the Lab module for **navify**® Integrator
- Available connectivity scenarios to connect applications via Lab module for **navify**® Integrator, as well as the actions to take in each scenario.

The **Data specification** document describes the data elements used during message exchanges between the Lab module for **navify**® Integrator and the host system (LIS, middleware, etc.) to enable Roche to collect data from Roche analyzers in order to understand instrument activity.

The **User Assistance** contains information about the product, including:

- Background information
- Routine operation

Privacy notice

When you use the User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged.
The data collected is for Roche internal use only. It is never forwarded to third parties. It is anonymized, and

after 1 year it is automatically deleted.
Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

⚠ General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

⚠ Incident reporting

- Inform your Roche Service representative and your local competent authority about any serious incidents which may occur when using this product. Note that since Lab module for **navify**® Integrator enables access to other applications, you will be required to report incidents with the enabled application instead.

Images

The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty

Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative, or perform such updates with their assistance.

Roche-provided hardware firewall

The Roche-provided hardware firewall provides a network barrier between Roche systems and the customer network to protect Roche products from network-borne attacks.

- As a key element in the Roche strategy for securing and protecting its systems, the Roche-provided hardware firewall must not be removed.

- The use of the Roche-provided hardware firewall requires you to assign static IP addresses to Roche products. The static IP addresses ensure that Roche products work properly.

License information

Lab module for **navify®** Integrator software is protected by contract law, copyright law, and international treaties. Lab module for **navify®** Integrator contains a user license between F. Hoffmann-La Roche Ltd. and a license holder, and only authorized users may access the software and use it. Unauthorized use and distribution may result in civil and criminal penalties.

Open-source and commercial software

Lab module for **navify®** Integrator may include components or modules of commercial or open-source software. For further information on the intellectual property and other warnings, as well as licenses pertaining to the software programs included in Lab module for **navify®** Integrator, refer to the electronic distribution included with this product.

This open-source and commercial software and Lab module for **navify®** Integrator as a whole can constitute a device regulated in accordance with applicable law. For more information, refer to the corresponding user documentation and labeling.

Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to Lab module for **navify®** Integrator.

Trademarks

NAVIFY is a trademark of Roche.

All other product names and trademarks are the property of their respective owners.

Feedback

We have made every effort to make sure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. If you have any such feedback, contact your Roche Service representative.

Disclaimer

This publication may contain information and references to products that may not be available in your country.

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eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on **navify**® Portal:

www.navifyportal.roche.com

For more information, contact your local affiliate or Roche Service representative.

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Intended use

Lab module for **navify**® Integrator is a software platform intended to provide bidirectional, standardized and secure data integration and communication between laboratory data sources (Instruments, LIS, HIS, EMRs) and to cloud-based products.

Lab module for **navify**® Integrator is not intended as a primary diagnostic tool by physicians or to be used as a substitute for professional healthcare advice. It is not intended to interpret or analyze clinical laboratory test or other device data, results, or findings. It is not a substitute for a customer's primary data sources.

Symbols and abbreviations

Symbols used in the publication

Symbol	Explanation
•	List item
	Cross-reference to another topic
	Figure, used in figure titles and cross-references to figures
	Table, used in table titles and cross-references to tables
	Tip, used for extra information on correct use or for useful hints
	Extra information within a task
	Result of an action within a task
	Materials that are required for a task
	Prerequisites of a task

Symbols used in the publication

Symbols used on product

Symbol	Explanation
	Global Trade Item Number

Symbols used on product

Symbol	Explanation
	Serial number
	Manufacturer
	Date of manufacture
	Authorized representative in the European Community
	Consult instructions for use or consult electronic instructions for use
	Eurasian Conformity

Symbols used on product

Abbreviations

The following abbreviations are used in this publication:

Abbreviation	Definition
CPU	Central processing unit
DNS	Domain name system
EC	European Community
GB	Gigabyte
HTTP	Hypertext transfer protocol
IP	Internet protocol
IT	Information technology
MB	Megabyte
OS	Operating system
PDF	Portable document format
RAM	Random access memory
RLN	Roche laboratory network
SSL	Secure sockets layer
TCP	Transmission control protocol
UDP	User datagram protocol
UEFI	Unified Extensible Firmware Interface

Abbreviations

Abbreviation	Definition
VM	Virtual machine

Abbreviations

Installing the software module

To install the Lab module for **navify**® Integrator software module, a cluster must first be created using a Unified Gateway or an on-premises virtual machine. Once the cluster is running, the software module can be deployed onto it.

The Unified Gateway installation pathway is suitable for the following scenarios:

- Customers cannot provide hardware servers
- Customers' virtual hardware has limited capacity
- Customers have special IT requirements for servers running in their own network
- Services module for **navify**® Integrator is already installed and can be used from an infrastructure perspective

The virtual machine installation pathway is suitable for the following scenarios:

- Customer-hosted virtual machines support better high availability when using a professional hypervisor technology
- Use cases where data sources are mostly in the customer network
- Future scaling should be done via virtual servers

- Customer wants to reduce physical infrastructure on-premise

Your Roche Service representative can give you additional guidance on which installation pathway best suits your needs.

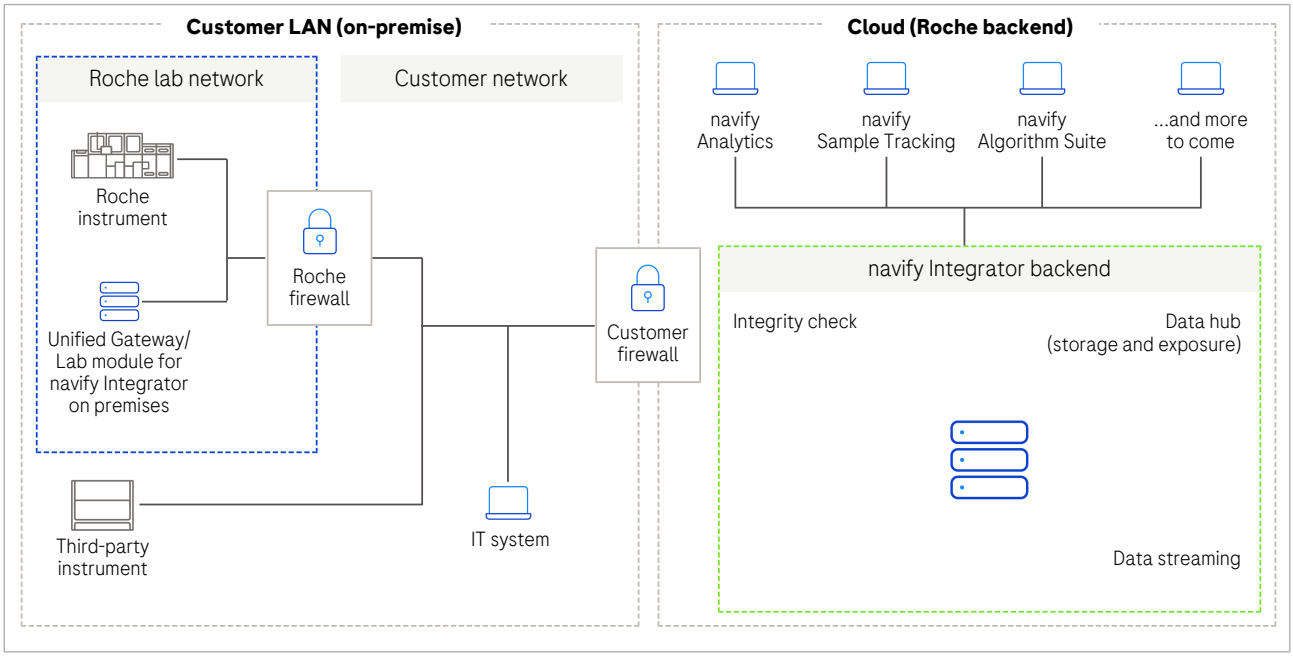
In this section

Unified Gateway

Installation on a Unified Gateway

In this deployment scenario, the Unified Gateway serves as a base upon which the cluster infrastructure and on-premises services can be deployed. Any other compatible software that you require can also be deployed upon this base if Roche has preapproved and/or tested the software to be installed on the Unified Gateway.

Once configured by Roche, the Unified Gateway is taken to the customer site and installed within the Roche Lab Network (RLN), which is protected by a Roche-provided firewall.



Unified Gateway connectivity requirements

For more information on the connectivity requirements, refer to the Lab module for **navify®** Integrator Cybersecurity and Connectivity brochure. Your Roche Service Representative can provide you with the brochure.

Your network must fulfill the following requirements:

- Bandwidth of at least 50 Mbps (6.25 MB/s)
- **Network configuration**: Your network must be configured to allow communication between the customer network and the internet (Roche backend) for the following protocols, IP addresses, and ports:

System	URL	IP address	Port	Type	Description
Lab module for **navify®** Integrator and Services module for **navify®** Integrator	*.navify.com	193.58.155.0/24	443	Cloudflare	**Bidirectional communication is required**. Main connection enabling Lab module for **navify®** Integrator and Services module for **navify®** Integrator.
Services module for **navify®** Integrator and FortiGate		193.228.103.0/24	*	Cloudflare	Dedicated connections enabling UDP or TCP traffic for Services module for **navify®** Integrator and FortiManager.
Services module for **navify®** Integrator	remoteservice-gas1.roche.com	62.209.44.21	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas2.roche.com	62.209.44.22	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas3.roche.com	209.202.167.19	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas4.roche.com	209.202.167.20	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas5.roche.com	120.136.45.231	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas6.roche.com	120.136.45.230	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas15.roche.com	35.76.193.4	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas16.roche.com	52.193.219.53	443	Direct	Dedicated connections enabling Remote Support
Fortimanager (required only for Unified Gateway deployments)	rln-cm-**.dia.roche.com	52.178.37.238	514/541	Direct	Dedicated connections enabling Roche-provided firewall management

Network configuration requirements

Additional considerations

- Customer HTTP proxy: Supported
- SSL inspection: Not supported

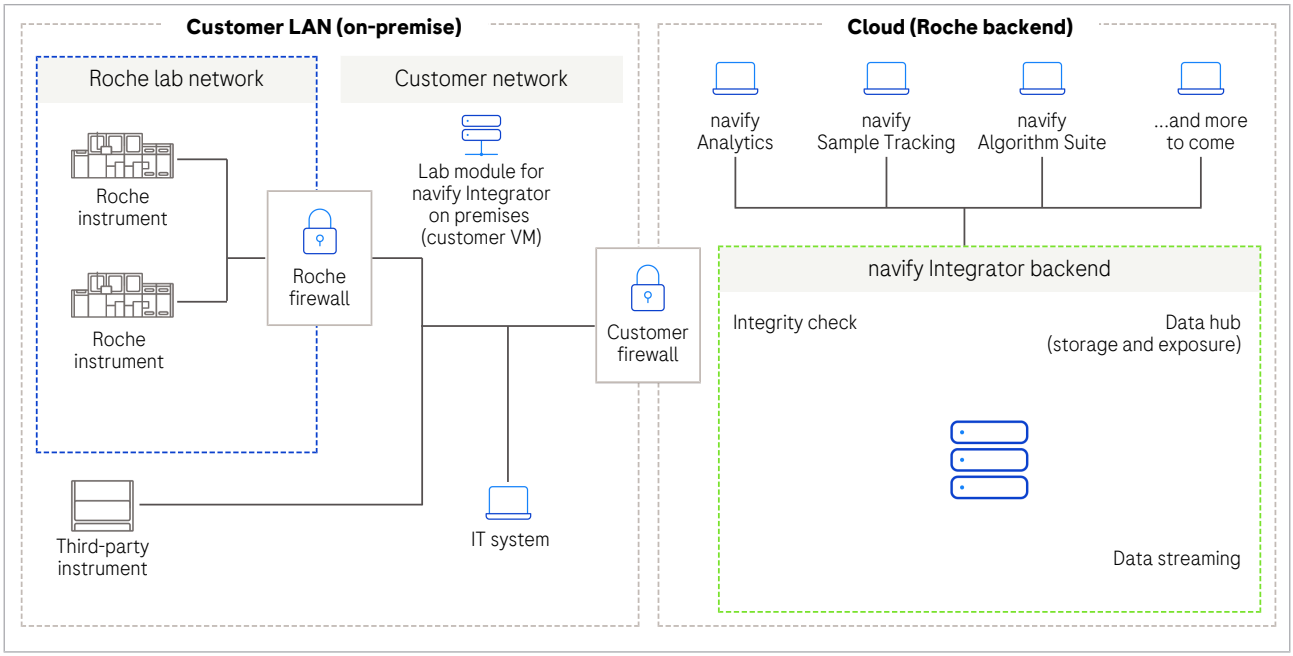
Virtual machine

In this section

Installation on a virtual machine

In this deployment scenario, the virtual machine is hosted within the customer network and serves as a base upon which the cluster infrastructure and on-premises services can be deployed.

The customer is responsible for the security and compliance of the customer-provided infrastructure layer onto which Roche installs software. Roche is only able to ensure security and compliance from the operating system (OS) layer upwards of software installed on the provided virtual machine.



Specifications of the virtual machine

Configure the following specifications:

- 500 GB of disk space
- 8 core processors
- 32 GB of RAM at minimum
- OS: Linux 64 bit
- UEFI boot enabled

The specifications of the virtual machine may need to be increased, depending on the applications that will run on it. Confirm the resource requirements with your Roche Service representative before proceeding.

Virtual machine connectivity requirements

For more information on the connectivity requirements, refer to the Lab module for **navify®** Integrator Cybersecurity and Connectivity brochure. Your Roche Service Representative can provide you with the brochure.

Your network must fulfill the following requirements:

- Bandwidth of at least 50 Mbps (6.25 MB/s)
- **Network configuration**: Your network must be configured to allow communication between the customer network and the internet (Roche backend) for the following protocols, IP addresses, and ports:

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Services module for **navify®** Integrator and FortiGate		193.228.103.0/24	*	Cloudflare	Dedicated connections enabling UDP or TCP traffic for Services module for **navify®** Integrator and FortiManager.
Services module for **navify®** Integrator	remoteservice-gas1.roche.com	62.209.44.21	443	Direct	Dedicated connections enabling Remote Support
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	remoteservice-gas4.roche.com	209.202.167.20	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas5.roche.com	120.136.45.231	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas6.roche.com	120.136.45.230	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas15.roche.com	35.76.193.4	443	Direct	Dedicated connections enabling Remote Support
	remoteservice-gas16.roche.com	52.193.219.53	443	Direct	Dedicated connections enabling Remote Support

Network configuration requirements

System	URL	IP address	Port	Type	Description
Fortimanager (required only for Unified Gateway deployments)	rln-cm-**.dia.roche.com	52.178.37.238	514/541	Direct	Dedicated connections enabling Roche-provided firewall management

Network configuration requirements

- **Static IP addresses**: Within the customer network, you must reserve static IP addresses for the cluster:
  Virtual IP addresses:
  - 1 IP address for DNS traffic (UDP/53)
  - 1 IP address for TCP traffic to ports 80, 443, 50000-50100
  - 1 IP address for UDP traffic to ports 51000-51100
  - 1 IP address for Talos cluster access
  Node IP addresses:
  - 1 IP address for the node

  All IP address addresses must be in the same subnet and it must be guaranteed that no other device uses them.

Additional considerations

- Customer HTTP proxy: Supported
- SSL inspection: Not supported
- DNS delegation: DNS delegation can be optionally enabled for any customer server or router towards the VM. At this stage, we recommend enabling DNS delegation, as the cluster infrastructure may use it in the future. If DNS resolution to services on the cluster is required, you must define and provide a domain name (such as *.rochegateway.lab.com), and also add delegation of that domain name as a record to your DNS server.

Creating a virtual machine

This procedure is only relevant if you chose the virtual machine installation pathway.

To create the virtual machine, use your preferred hypervisor software. The following hypervisors have been tested:

- VirtualBox
- Hyper-V
- VMware Workstation (Windows)
- VMware Fusion (MacOS)
- VMware vSphere

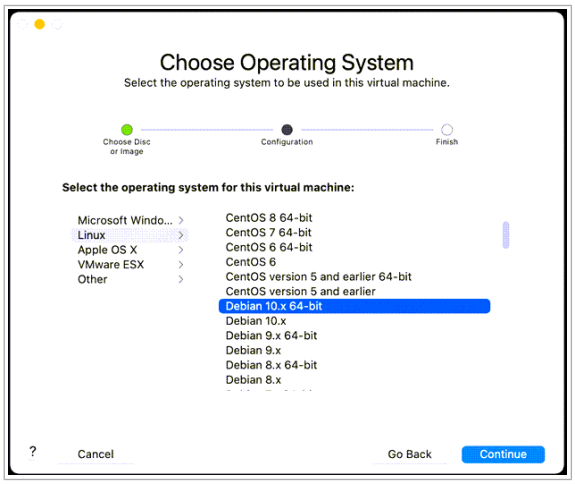
The above listed hypervisors were tested and validated once. Contact you Roche service representative for support if you have any issues with these or other hypervisors.

Hypervisors other than those listed above can be used, however unforeseen problems may occur.

The screenshots below are provided only for illustrative purposes, using several different types of hypervisor as examples.

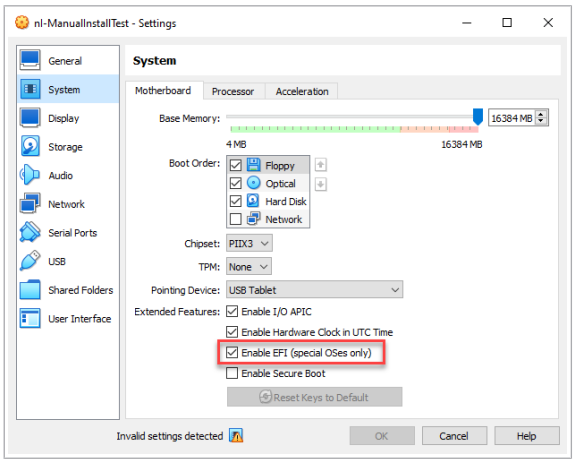
- One of the above listed hypervisor software
- Specifications from *Specifications of the virtual machine (14)*

Creating a virtual machine



1 Using the hypervisor of your choice, create a virtual machine.

   You can find the specifications in *Specifications of the virtual machine (14)*.



2 Configure the virtual machine to support the Unified Extended Firmware Interface (UEFI).

   Secure Boot is not supported.
   For increased security, we highly recommend encrypting the virtual machine's hard disk.

3 Enable hardware acceleration on your virtual machine, if available.

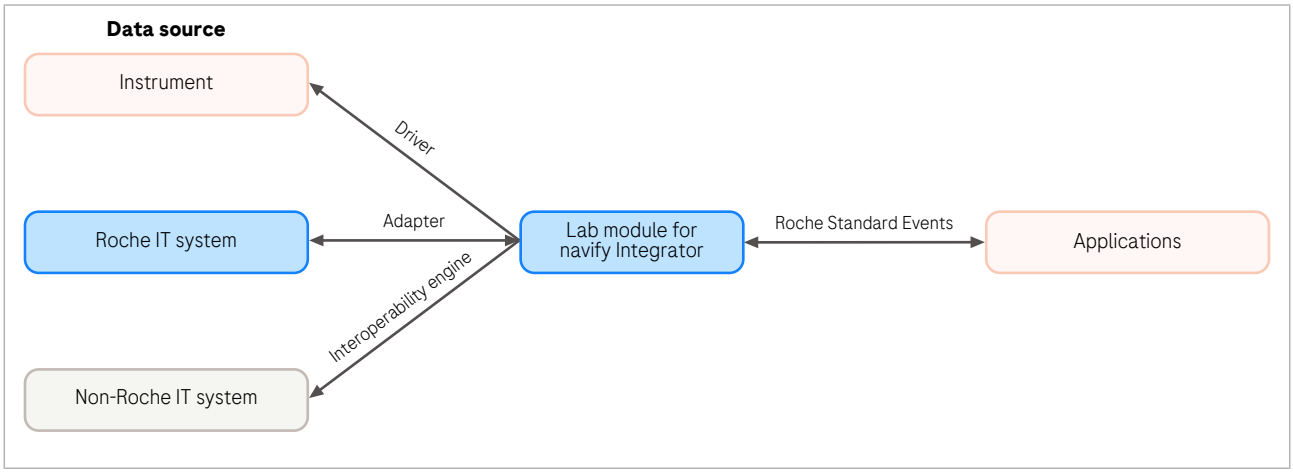
4 Continue configuration of the CPU, memory, and disk size in accordance with the current recommendations:
   - 500 GB of disk space
   - 8 core processors
   - 32 GB of RAM minimum

   ➔ The virtual machine is created.

The specifications of the virtual machine may need to be increased, depending on the applications that will run on it. Confirm the resource requirements with your Roche Service representative before proceeding.

Connectivity between the data sources, Lab module for navify® Integrator, and applications

The Lab module for **navify®** Integrator enables the connection from the data source to applications.



The interface between the data source and the Lab module for **navify®** Integrator depends on the data source type:

- **Instruments**: Driver
- **Roche IT system**: Adapter
- **Non-Roche IT system**: Interoperability engine

In this section

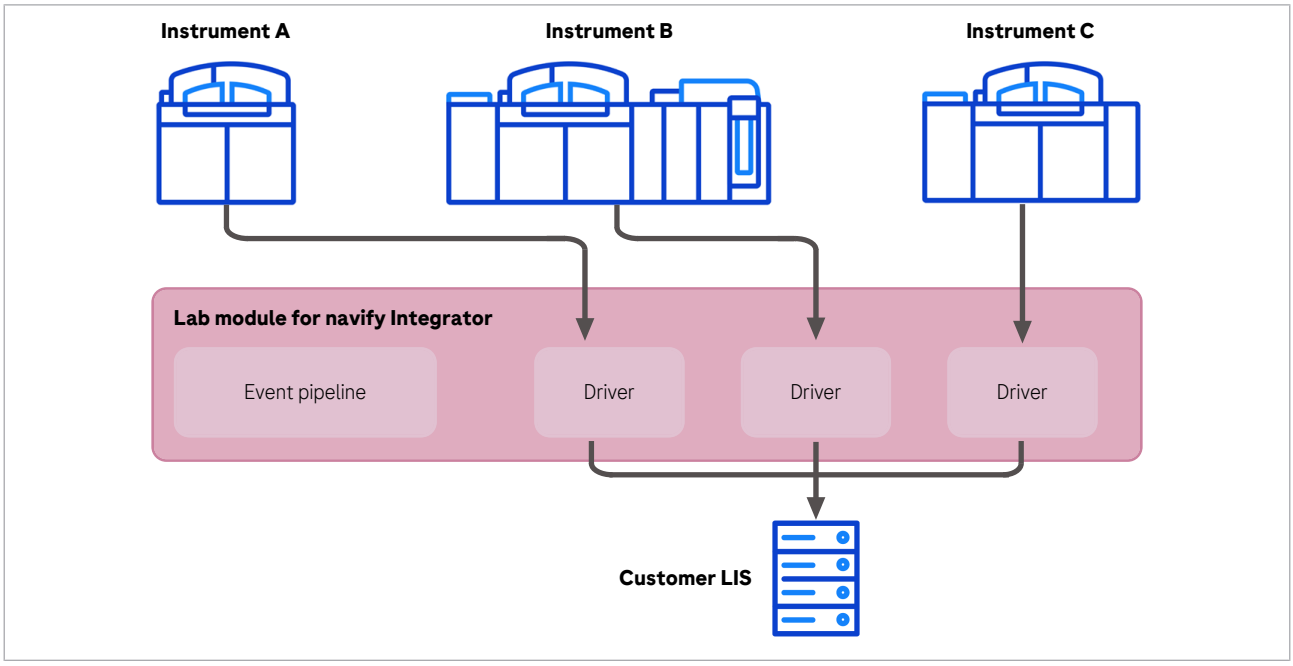
Connection to instruments

Technical requirements

To connect to an **instrument**, there are no customer actions required since the driver is provided by Roche and the configuration of the instrument is performed by your Roche Service representative or the third-party instrument representative.

Network view

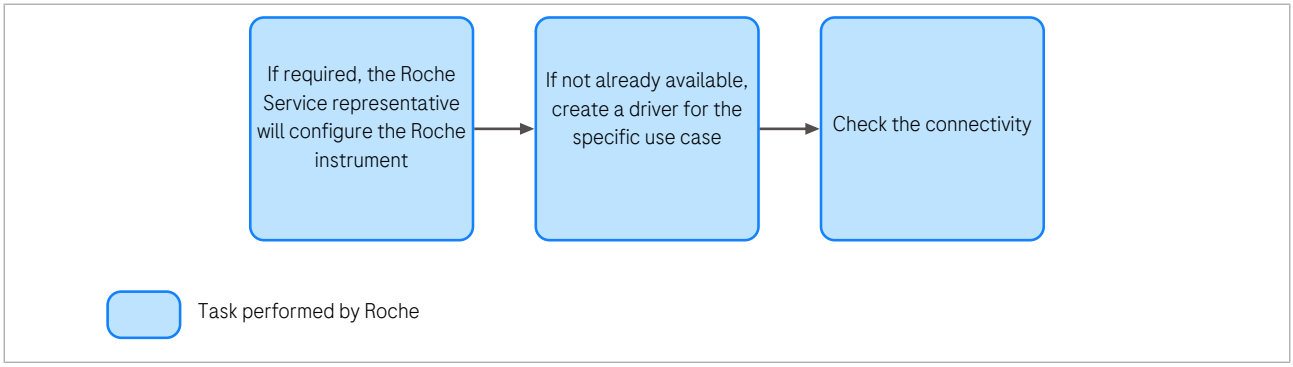
The diagram below shows the network view of the connection between the instrument and the Lab module for **navify**® Integrator:



Implementation process

When connecting to an instrument, Roche performs the complete implementation process.

For more information on the data that Roche collects to enable the functioning of the connected application, refer to the **Data specification** corresponding to the application.



Implementation process to connect to an instrument

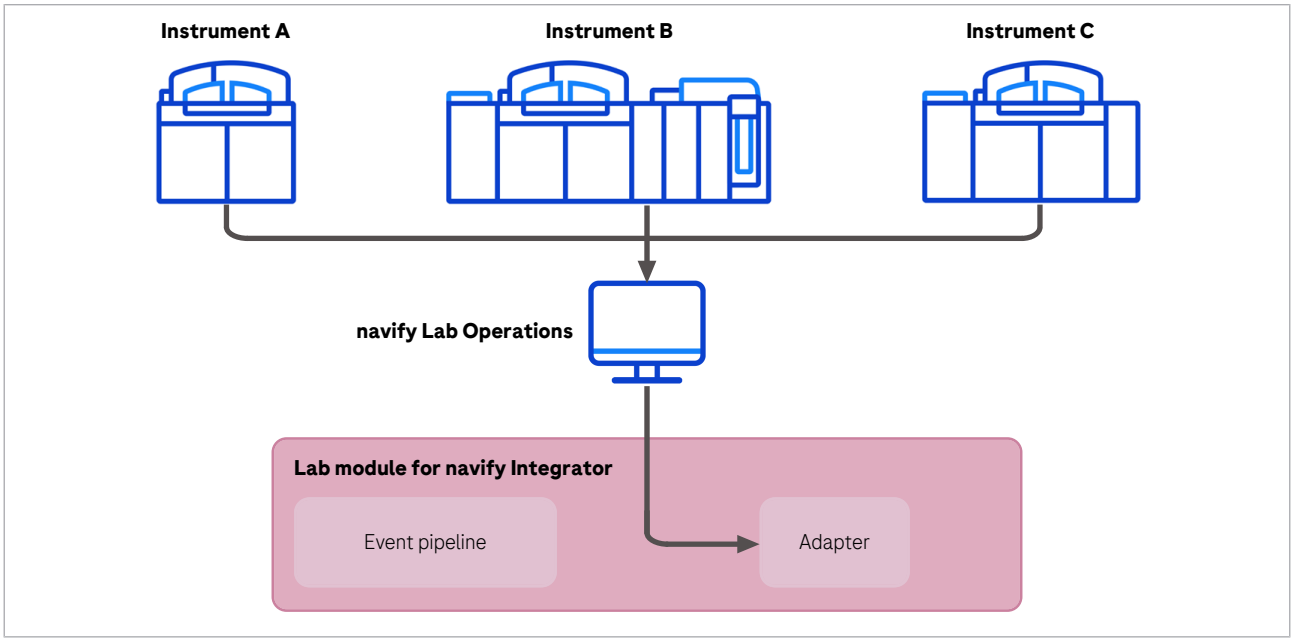
Connection to Roche IT systems

Technical requirements

To connect to a **Roche IT system**, there are no customer actions required since the adapter is provided by Roche, and the configuration is performed by your Roche Service representative.

Network view

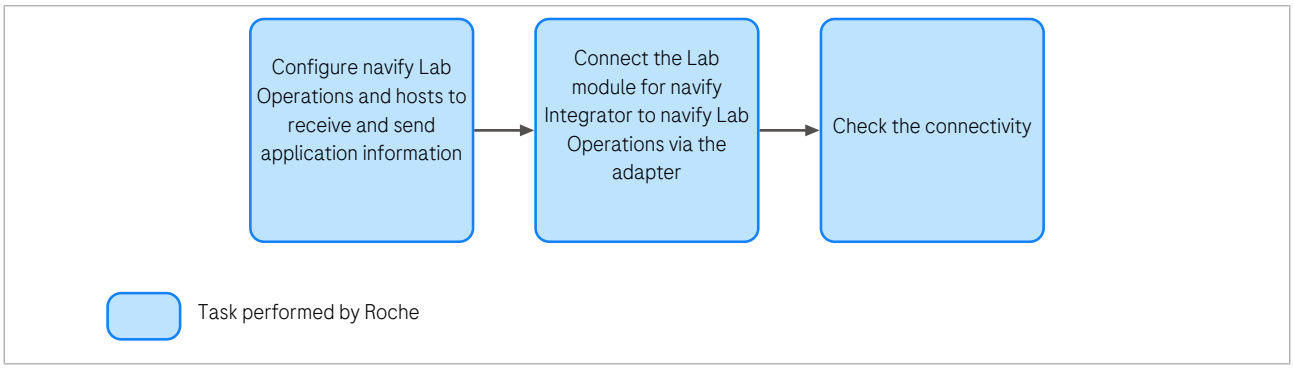
The diagram below shows the network view of the connection between a Roche IT system and the Lab module for **navify**® Integrator:



Implementation process

When connecting to a Roche IT system, Roche performs the complete implementation process.

For more information on the data that Roche collects to enable the functioning of the connected application, refer to the **Data specification** corresponding to the application.



Implementation process to connect to a Roche IT system

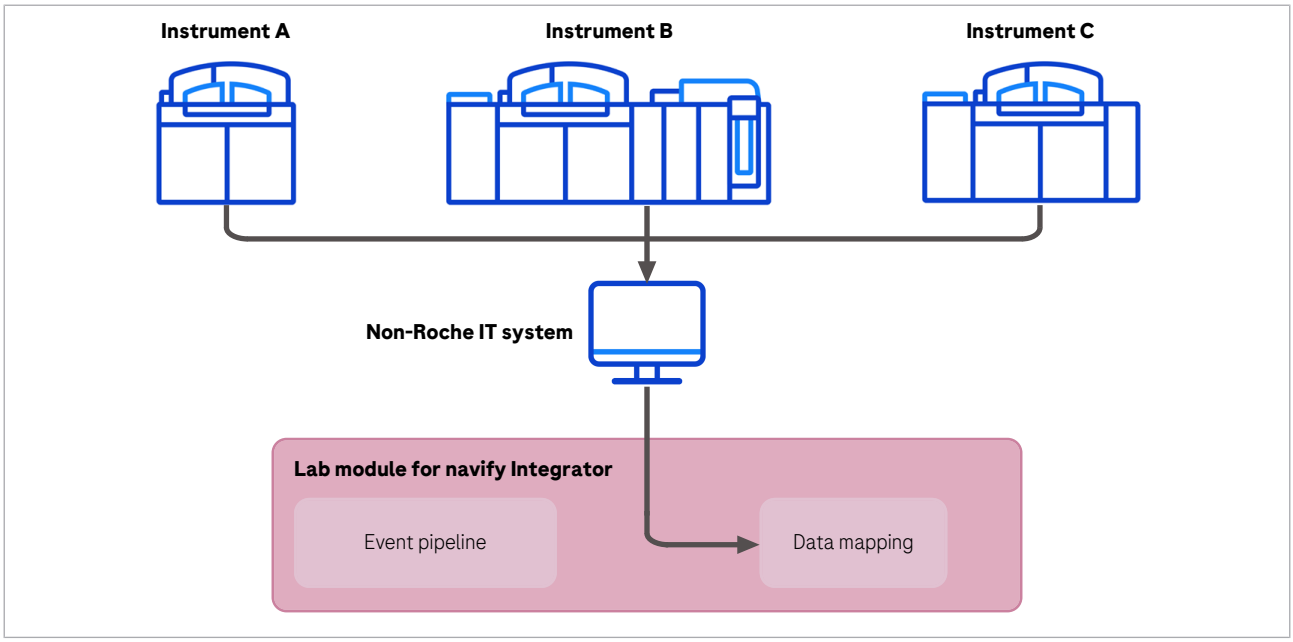
Connection to non-Roche IT systems

Technical requirements

To connect to a **non-Roche IT system**, you must ensure that the required data is exposed to the Lab module for **navify**® Integrator. Contact the provider of the non-Roche IT system to configure the settings so that the required data is accessible.

Network view

The diagram below shows the network view of the connection between a non-Roche IT system and the Lab module for **navify**® Integrator:



Implementation process

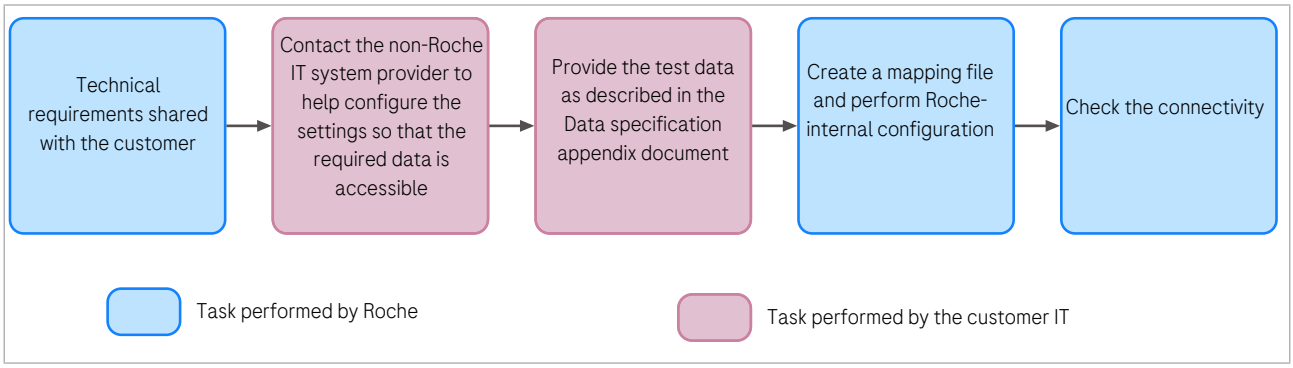
When connecting to a non-Roche IT system, the customer IT department must provide the required data for the corresponding application.

The data required to connect to a non-Roche IT system depends on the connected application. You can find a list of the required data in the **Data specification** corresponding to the application you would like to enable.

Once defined, the data format must remain the same to prevent connectivity issues.

First, the customer IT department must provide example data in the exact format that it will be exposed to the Lab module for **navify**® Integrator by the non- Roche IT system. The example data must be the exact format that

will be sent to Lab module for **navify**® Integrator during normal operation. If you cannot provide example data, provide interface definitions of the format that the data will be sent in. Then, using this test data, Roche creates a mapping file and performs any necessary configuration steps. At the end of the process, Roche checks the connectivity to ensure that the connection is successful and data can be sent and received.



Implementation process to connect to a Non-Roche IT system

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