# User manual
## SHARAZONE

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## DOCUMENT HISTORY

| Version | Author | Changes |
|---|---|---|
| **0.01** | Anne-Gaëlle Bergé | Create document |
| **1.0** | Anne-Gaëlle Bergé | Integrate comments from the Taskforce |
| **1.1** | Anne-Gaëlle Bergé | Add rules on naming convention for Shared test inputs |
| | | |

# INDEX

# 1   Definitions

The terms in this section are *highlighted* in the document for the read to refer to their definition.

- ⭕ *Test Item:* Structured healthcare information that is exchanged. This includes DICOM images and other DICOM Information Objects. It is likely in the future that other formats such as CDA documents or FHIR bundles may be included with a revision to this contract. Under no circumstances, a Test Item will contain or refer to Personal Data. Note: This essentially means that test items have to be artificially created and/or imaging data created from phantoms.

- ⭕ *Test Suite:* List of test scripts or test procedures to be executed by the consumer on the Test Item. Each Test Suite includes evaluation criteria. This document is also used by the Consumer to document the outcome of the testing performed on the Test Item as a Test Report.

- ⭕ *Shared Test Input:* A ZIP archive containing the Test Item and the Test Suite.

- ⭕ *Product:* A product that a vendor or open-source developer produces and distributes. Products are characterized by a name, version and are provided by a well identified organisation, and can be Creator Products or Consumer Products.

- ⭕ *Organisation:* The designer (manufacturer, vendor, open-source issuer, etc…) of a Product that creates or consumes the Shared Test Input.

- ⭕ *Participant:* An Organisation that subscribes to the IHE SHARAZONE to test one or more of its Products.

- ⭕ *GDPR:* Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

- ⭕ *Personal Data:* data as defined by article 4 (1) of the GDPR

- ⭕ *Participant Staff Personal Data:* Personal Data which concerns the employees, agents or subcontractors of the Participant.

- ⭕ *Creator Product:* The Product that composes the Shared Test Input.

- ⭕ *Creator Participant:* Participant who intends to register Creator Products

- ⭕ *Consumer Product:* The Product that consumes the Shared Test Input.

- ⭕ *Consumer Participant:* Participant who intends to register Consumer Products

- ⭕ *Users:* Personnel from a Participant.

- ⭕ *Moderator:* Oversees the day-to-day operational aspects of managing the testing service, such as, approval of registered Products, test monitoring and moderation, participant account management and contract distribution.

- ⭕ *Repository:* A central (virtual) location of Shared Test Inputs with searching and reporting capabilities that enables IHE SHARAZONE Participants to collaborate.

- ⭕ *Test Report:* Documentation summarizing test activities performed in following the test script and test procedures described in the Test Suite. The Test Report is derived from the Test Suite and might include screenshots of the Consumer Product.

○ *Product Lifecycle:* Maturity of the Consumer Product or the Creator Product version that created or processed the Test Item(s), e.g. in development, released, obsolete.

○ *Working days:* days as defined in Commission Regulation (EC) No 802/2004 of 21 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings.
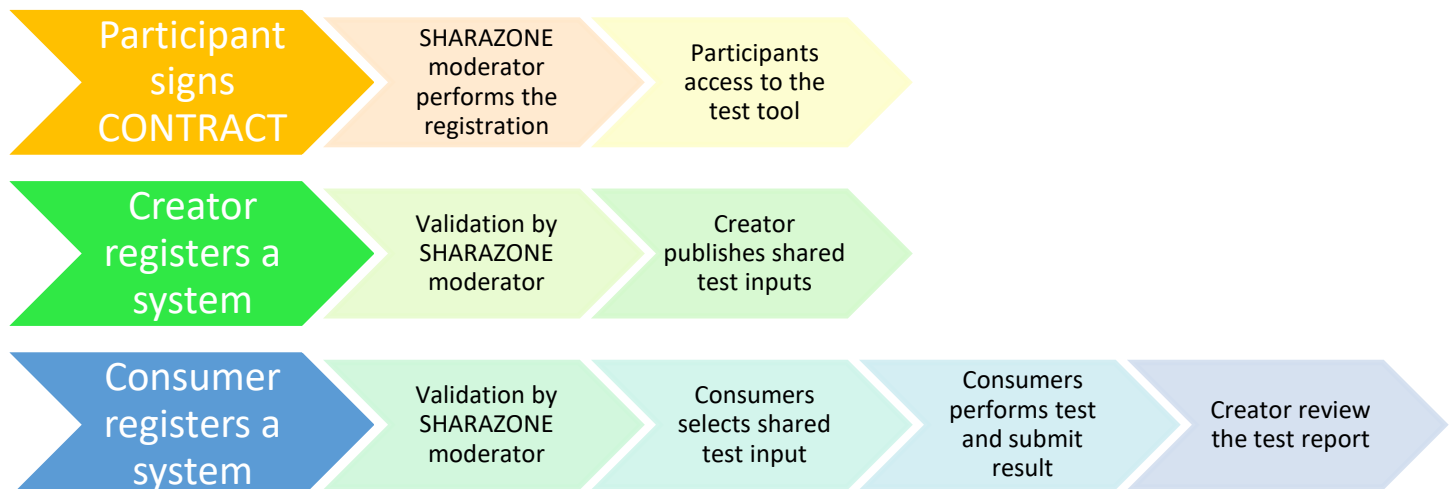
# 2   Description of SHARAZONE process

## 2.1   SHARAZONE purpose

SHARAZONE is a continuous asynchronous testing service offered by IHE Services. Initially, it is targeting to medical software in the DICOM field.

The testing strategy offered by SHARAZONE is as follows:

- Medical software vendor willing to participate to SHARAZONE subscribe to the service as creator, consumer, or both;
- *Creator participants* offer *Shared Test Inputs* to SHARAZONE members acting as consumers;
- *Consumer participants* pick the *Shared Test Inputs* of interest, process them according to the *test suite* included in the package and submit their test reports;
- Creator and Consumer *participants* can discuss the output of the test in a one-to-one way.
- A SHARAZONE *moderator* is available in case of issue or dispute.

## 2.2   Process overview

| Participant signs CONTRACT | SHARAZONE moderator performs the registration | Participants access to the test tool | | |
|---|---|---|---|---|
| Creator registers a system | Validation by SHARAZONE moderator | Creator publishes shared test inputs | | |
| Consumer registers a system | Validation by SHARAZONE moderator | Consumers selects shared test input | Consumers performs test and submit result | Creator review the test report |

## 2.3   SHARAZONE support tool

SHARAZONE support tool is Gazelle Test Management. This tool from the interoperability test bed is dedicated to the management of the testing session. SHARAZONE testing environment is available at https://sharazone.ihe-europe.net.

# 3   How it works in practice

## 3.1   Participant signs contract

As a first step, companies willing to participate in SHARAZONE shall contact IHE-Europe and return SHARAZONE contract. When filling out the form, the company shall decide whether it subscribes to the service as Creator, Consumer, or both.

## 3.2   Participant registration in Gazelle Test Management

The registration of the *organisations* within Gazelle Test Management is delegated to the SHARAZONE *moderator*. Thus, we ensure that only the *organisations* with an ongoing subscription can access the tool. It is a way to make the *Shared Test Inputs* private to SHARAZONE member.

Upon receipt of the contract by IHE-Europe secretariat and payment of the participation fee, the SHARAZONE *moderator* **will register the** *organisation* **within Gazelle Test Management as well as the main point of contact**. This first user will be designated as the *organisation* administrator within Gazelle Test Management. Responsibilities can be changed later on by SHARAZONE *moderator* or by one of the *organisation*'s administrators.

When the *user* is registered, an email is sent which contains a link for the user to define a password.

If more people need to have access Gazelle Test Management, it is the responsibility of the *organisation*'s administrator to create accounts for them. *Users* are also able to register on their own. In that case, an email is sent to the *organisation*'s administrators to validate the creation of the accounts.

User management feature is available from menu **Registration > Manage users**.

For further details about the creation of accounts in Gazelle Test Management, read the user manual. The sequence diagram in Appendix A summarizes the steps of the registration process.

## 3.3   System registration in Gazelle Test Management

In the context of SHARAZONE, **a system in Gazelle Test Management represents a dedicated version of a** *product*. This *product* can be commercially released or not. If the *participant* wants to offer *Shared Test Inputs* from several versions of the same *product*, it is agreed among *participants* that each version of the *product* will be represented by a system in Gazelle Test Management.

As of April 2021, only DICOM *Shared Test Inputs* are in the scope of SHARAZONE. As a consequence, there is currently only one testing session in Gazelle Test Management, entitled DICOM, and it is the default one when a  user logs into the tool for the first time. In the future, one shall make sure he/she registers his/her system in the appropriate testing session.

### 3.3.1   How to

A new system can be added from menu **Registration > Manage systems**. Click on "Add a system" to create a new one. To edit an existing entry, use the pencil icon.

Gazelle Test Management has not been fully adapted to support SHARAZONE yet. As a consequence, the following conventions apply as a work around:

In the Summary tab:
- **System/product name**: enter the commercial (development) name of your product
- **System type**: available values are PACS, MOD (for modality), and WS (for work station). If none of those matches your system, get in touch with the Sharazone administrator, it is possible to add others.
- **System keyword**: reuse your product name and append the version number. Length of this field is limited to 20 characters, you might need to truncate your product name.
- **Version**: The *product lifecycle* status of the system (Commercially released, Not yet release, Obsolete) shall be put into bracket after the version value in the "Version" field.
- **Integration statement's date**: Input the release date of the *product*
- **Owner**: Select the main point of contact for any questions related to the *product*.

| | |
|---|---|
| Organization Name | IHE-EU |
| System/Product name * | GE_GSPS_labeling_app |
| System type * | CONTENT_CREATOR |
| System keyword | CONTENT_CREATOR_IHE-EU_  GE_GSPS_labeling |
| Version | NA [Not yet releases] |
| HL7 Conformance Statements ❓ | ➕ Add a document with HL7 conformance statements |
| DICOM Conformance Statements ❓ | ➕ Add a document with DICOM conformance statements |
| Link to IHE Integration Statement ❓ | |
| Integration Statement's date | 📅 |
| Testing session | DICOM |

In the Profiles/Actors tab:
- If your product creates DICOM objects, select Profile: DICOM, Actor: CONTENT_CREATOR
- If your product consumers DICOM objects, select Profile: DICOM, Actor: CONTENT_CONSUMER

Click on this link to add IHE implementations (Actors / Integration Profiles / Integration Profile Options) to this system.

| Search Criteria | | | | | |
|---|---|---|---|---|---|
| Domain | Show all | ✖ | Actor | Show all | |
| Integration profile | Show all | ✖ | Int Prof. option | Show all | |

| Integration profile ▲ | Actor ⬍ | Integration Profile Option ⬍ | Add this IHE implementation to this system |
|---|---|---|---|
| DICOM | Consumer | None | Add this IHE implementation to this system |
| DICOM | Creator | None | Add this IHE implementation to this system |

Obviously, your system can act as both CONTENT_CREATOR and CONTENT_CONSUMER.

In the DICOM tab, you are free to share your Skype account if you want others to be able to directly get in touch with you.



For further details about the creation of systems in Gazelle Test Management, read the dedicated section of the user manual.

Once your system is created within Gazelle Test Management, get in touch with SHARAZONE *moderator* (sharazone-admin@ihe-europe.net). The *moderator* will double check that the system(s) you have registered complies with your subscription. If they did, the system(s) will be accepted into the session and thus appear as a test partner to other *participants*.

## 3.4 Shared Test Inputs creation

### 3.4.1 General consideration

For a given product / version the recommendation to the creator is to include all features to be tested in a single test input, meaning a single test suite. For example if you want to test the capability of the consumer to ingest and display datasets with various Transfer syntaxes this can be combined in the same test input / test suite. The benefit being that in one test report the creator have a complete view of the capability of the consumer product. Of course, in some cases the creator might want to create more than 1 test input for the same product / version. For example, in an early stage one want to get feed-back on an important feature, and then later on test the other features.

### 3.4.2 Step-by-step

The Samples section of Gazelle Test Management is used to store and reference all the *Shared Test Inputs* that the *Creator Participants* make available. For a full description of the Samples section, read the dedicated section within the user manual.

To register a new *Shared Test Input*, go to **Connectathon > Connectathon > List of samples**.

In the drop-down list, select the *creator product* of interest. In the "Samples to share" tab, the "Shared Test Input - DICOM" entry shall appear. Click on the + sign to register a new entry.

Edit an attribute associated to : Shared Test Input - DICOM

summary | file(s)

**Name**

GSPS_labels

**Description**

Summary of the content of the **Shared Test Input**: Summarize that is included in the shared test input and what you expect from other participants.

**List of files:**
- Test Suite.docx
- plomoGsps2Layers.tar.gz
- plomoGsps.tar.gz

*Whether you have deadline to met, do not hesitate to add details. Any other information you think is useful for the participant to know before downloading the shared test input.*

**Usage**

connectathon

**Sample is ready to be used by others systems** ☑

The following conventions apply:

- First of all, refer to the naming convention section to build the name of the Shared Test input;
- For sake of consistency, we ask you not to delete an entry unless it has not been used yet. On the contrary, you should rather update its name and prefix it with [Withdrawn] so that nobody uses it.
- In the description text area, give as much details as you think are useful for the *consumer participants* to understand your expectation and the work to be performed. In addition, list of the files included in the archive along with a description for each of them.
- In the "File(s)" tab, upload
  - The ZIP archive that contains the DICOM objects to be consumed and the *Test Suite* as a MS Word document
  - The *Test Suite* as a MS Word document (we ask you to provide it also outside of the ZIP archive for *participants* not to download gigs of data if it appears that they will not be able to execute the *Test Suite*.) A template for a basic test suite is given in Appendix B - Basic Test Suite Template.
  - If available, the DICOM metadata for the DICOM objects within the ZIP archive. Once again, the purpose is to allow *consumer participants* to better understand the content to be tested.

The ZIP Archive shall have the following structure:

```
sharedTestInput.zip
        |_ImageSet1
        |__ object1.dcm
        |__object2.dcm
        |_ImageSet2
        |__object3.dcm
        |_TestSuite.docx
```

When your *Shared Test Input* is ready for others to consume it, make sure you have checked the option "Sample is ready to be used by others systems". Not ready samples appear in red in your list and are hidden from *consumer participants*.

After you are done with the creation of the *Shared Test Input*, please inform the SHARAZONE *moderator* that new entries are available. For each of them, provide the permanent link.

Note that for privacy purpose, the "Advanced sample search" feature is disabled in the context of SHARAZONE.

### 3.4.3    Naming convention for shared test inputs

In order to ease the search of test input, the following syntax and naming convention must be followed:

MODALITY*–BODY_PART*–OBJ_TYPE* / free text.

Note that the sample name is limited to 255 characters.

Items with an asterisk are mandatory

**MODALITY**: List the Modality Types included in the study (ies) (It corresponds to the tag (0008,0060) modality) using the DICOM defined terms documented in DICOM part3: http://dicom.nema.org/medical/dicom/current/output/html/part03.html#sect_C.7.3.1.1.1

See excerpt below:



**BODY_PART:** list the body part included in the dataset (it corresponds to the tag (0018,0015)) using the DICOM Defined terms in DICOM par16 table L1, column **Body Part Examined**: http://dicom.nema.org/medical/dicom/current/output/chtml/part16/chapter_L.html#table_L-1

See excerpt below:

**Table L-1**. Corresponding Codes and Terms for Human Use

| Coding Scheme Designator | Code Value | Code Meaning | Body Part Examined | SNOMED-RT (Retired) |
|---|---|---|---|---|
| SCT | 818981001 | Abdomen | ABDOMEN | |
| SCT | 818982008 | Abdomen and Pelvis | ABDOMENPELVIS | |
| SCT | 7832008 | Abdominal aorta | ABDOMINALAORTA | T-42500 |
| SCT | 85856004 | Acromioclavicular joint | ACJOINT | T-15420 |
| SCT | 23451007 | Adrenal gland | ADRENAL | T-B3000 |
| SCT | 77012006 | Amniotic fluid | AMNIOTICFLUID | T-F1320 |
| SCT | 70258002 | Ankle joint | ANKLE | T-15750 |
| SCT | 128585006 | Anomalous pulmonary | | T-48503 |

**OBJ_TYPE**: List the type of dicom objects included in the dataset (images , video, Radiation Dose, Key Image notes etc…) using the following **keywords**:

| Keyword | Meaning |
|---|---|
| **IMAGS** | Single frame Images |
| **IMAGM** | Multi-frame Images |
| **VIDEO** | Video |
| **CAD** | Computer Aided Detection SR |
| **CDA** | Encapsulated CDA |
| **COMSR** | Comprehensive SR |
| **CSPS** | Color Presentation State |
| **DOSE** | Radiation Dose SR |
| **ENHSR** | Enhanced SR |
| **GSPS** | Grayscale Presentation State |
| **KIN** | Key Image note |
| **PDF** | Encapsulated PDF |
| **TEXT** | Basic Text SR |
| **WAVE** | Waveform objects such as Electrocardiograms, Hemodynamic, audio … |

**Free text**: optionally, you can enter free text if you feel it can help the consumer to understand better the content of the test input.

### 3.4.4 Example of test input syntax using naming convention

Direct radiography Chest images with Presentation state

**DX_PR**–**CHEST**–**IMAGS_GSPS**

Enhanced CT images of the Cervical Spine and the head with X-ray Dose SR and Presentation state

**CT_SR_PR**–**CSPINE_HEAD**–**IMAGM_DOSE_GSPS**

Images and video of the brain made with a NeuroChirurgy microscope modality

**GM**–**BRAIN**–**IMAGS_VIDEO**

2D and 3D Breast images with CAD SRs

**MG_SR**–**BREAST**–**IMAGS_IMAGM_CAD**/**2D and Breast Tomosynthesis Mammo**

## 3.5  Process test inputs as consumer and report results

Once your product is registered as DICOM CONTENT_CONSUMER in Gazelle Test Management, access the samples section from **Connectathon > Connectathon > List of samples**. Select the system you are working on from the drop-down list. For the "Samples available for rendering" tab, you will see all the available *Shared Test Inputs*.



For each *Shared Test Input*, the *creator participant* has put the *test suite* at your disposal outside of the ZIP archive. Do not hesitate to download it and have a look into it before you download the whole package. You might discover that it is not of interest to you.

When you have made your choice, go to the Connectathon testing page from menu **Connectathon > Connectathon > Connectathon** (or **CAT** shortcut in the top right corner). Select the system you are

| Profile ▲ | Actor ▲ | Profile Option ▲ | Type |
|---|---|---|---|
| DICOM | CONTENT_CONSUMER | NONE | T |
| Test | | Meta test | |
| SHARAZONE_TEST_PROCESS | | | ✚ |

working by clicking the + sign in front of the "SHARAZONE_TEST_PROCESS" test. Be careful to start the test for the CONTENT_CONSUMER actor. Actually, in case your *product* is both creator and consumer, you should see two entries for this test.

On the Start test instance page, click on the + sign below DICOM-CREATOR, and pick the *creator product* from the list. Confirm by clicking on "Add selected partners".



To complete the test instance creation, click on the play icon.



The test instance page is now displayed, follow the test instructions. You can also find the test instructions here.

Start a test immediately after you have downloaded the *Shared Test Input*. It will allow the *creator participant* to be notified that you will process his input. You always have the option to fail or abort the test in case you encounter any issue. When you do so, please enter the reason why. It will help the *creator participant* to improve the content he shares.

Mark the test instance as "to be verified" as soon as you have posted the *test report*.

Never hesitate to get in touch with the *creator participant*. Primary contact should take place through the chat window but you are allowed to contact him by email if you get no answer.

Never hesitate to report any issue to the SHARAZONE *moderator* (tooling issue, non-responsive test partner, and so on).

A sample test report is given in Appendix C - Example of a Test Report.

## 3.6  Review test report

As a *creator participant*, you will see test instances popping up for your *product* (in the SHARAZONE Gazelle instance, on the "Connectathon test page" which is used during IHE-Connectathons). Those are tests initiated by the *consumer participants*. Your peers might ask you questions through the chat window, please answer in a timely manner. When the test report is posted, the *consumer participant* is expected to mark the test as "to be verified". The SHARAZONE instance of Gazelle Test Management allows you to set the final status by yourself, no monitor will review the test instances or change the status.

Mark the test instance "Partially verified" when you download the test report. It allows the *consumer participant* to know that you are processing his input.

Mark the test instance "Verified" when you are done with reviewing the test report and that no further work is needed.

Do not hesitate to contact the *consumer participant* through the chat windows or via email.

Report any issue with the tooling or with the process to SHARAZONE *moderator*.

## 3.7  Notification system

To support SHARAZONE, and in particular the asynchronous way of testing, Gazelle Test Management can send you notification via email. You need to authorize Gazelle Test Management to send emails to

you. On the top-right corner, click on your user name and access your Preferences. From there, click on "Edit" and check the option "Send notification by email". Save.

At any time, you can suspend the notifications by email by editing your preferences and unchecking the option.
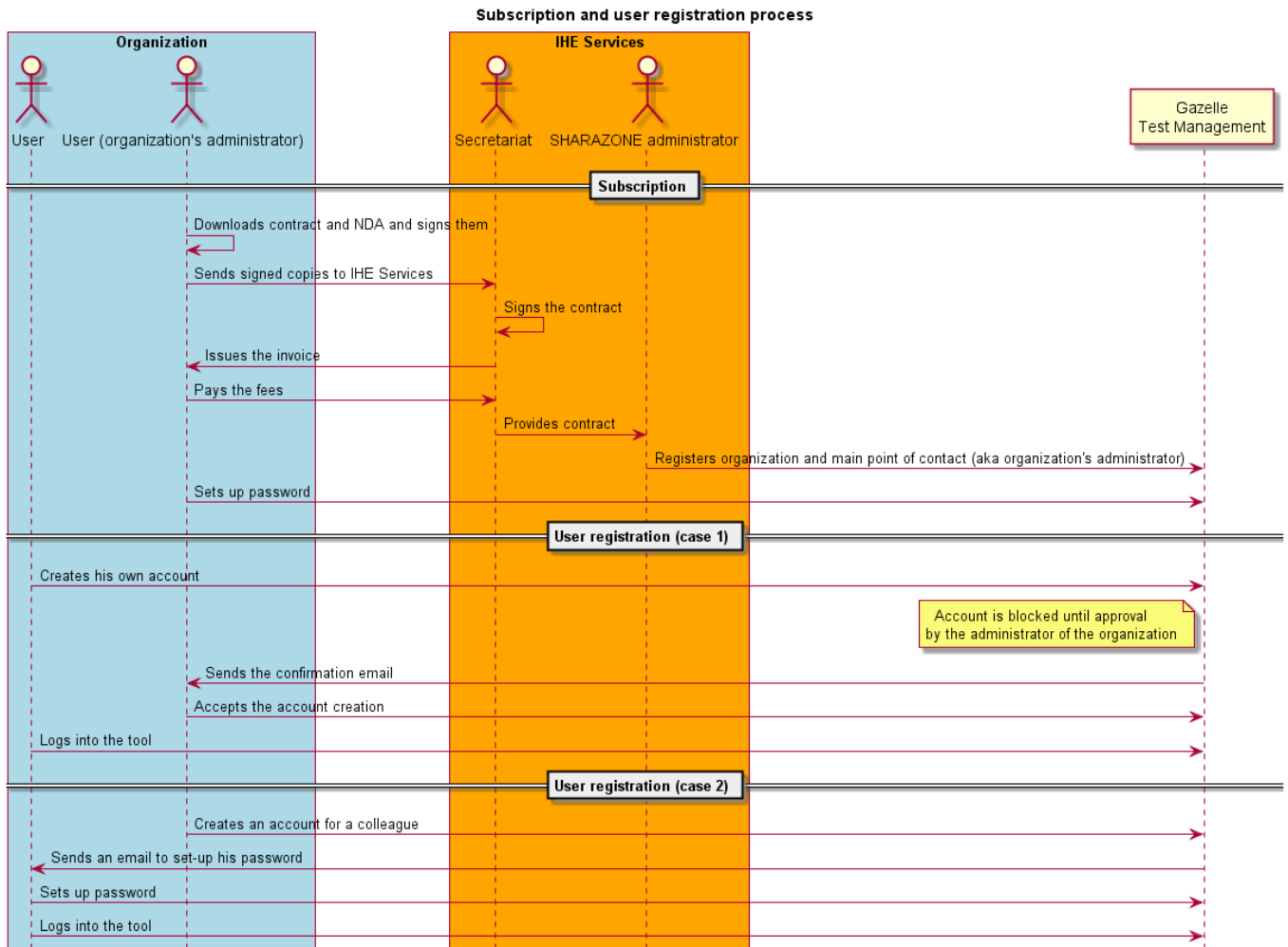
When notifications by email are disabled, you can still see the messages from Gazelle Test Management (Messages counter next to you username).

Notifications are sent / added to your message list when:

- Someone changes the status of a test instance (including the transition from no test to started) that involves your system;
- Someone adds a comment in the chat windows of a test instance that involves your system;
- Someone claims/releases a test instance that involves your system.

# 4    Appendices

## 4.1   Appendix A - User registration process



## 4.2   Appendix B - Basic Test Suite Template

A MS Word version of the template is available here.

## 4.3   Appendix C - Example of a Test Report

A MS Word version of a test report example is available here.