

eSanté LABO - Work Package WP2 - Use Cases

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Goal of the Document

This document describes how patients, general practitioners, laboratory personnel and other health care professionals will interact with the eSanté system and with each other when using and exchanging laboratory test results over the platform. It represents a requirements document at the behavioural level, which is an essential part in the requirements analysis process¹. Only when the major stakeholders agree on the use case descriptions in this document the analysis should advance to the more detailed functional and technical levels.

State of the Document

The information contained in this document reflects the status of an ongoing discussion within the LABO Work Groups, Such as the LABO LOINC Commission.
After having been reviewed and commented by representative members of all the major stakeholders of the LABO project, namely the Ministry of Health as well as private and public laboratories, version 2.0 of the document has been presented in the **CoPil CARA on 22/6/2011**, where it has been **validated**.

Change History

Version	Date	Author	Modification
0.1	10/12/2010	GBO	Initial draft
0.2	20/1/2010	GBO	Inclusion of remarks from RK and JCD
1.0	2/2/2011	GBO	Version presented at the Labo LOINC on 9/2/2011 and 9/3/2011
1.1	11/3/2011	GBO	Updated after the 2 previous Labo LOINC workgroups
1.2	30/3/2011	GBO	Integration of reviewer's remarks (RK,HZI, FWI, JCD). New front page layout for better compliancy with other eSanté deliverables. Completion and correction of distribution list.
1.3	1/4/2011	GBO	Some minor changes to make document compliant with LABO-WP2-UseCasePresentation-2.0.pptx Cancellation/Replacement use case: integration with LIS Moved Cancellation/Replacement use case into the data provider section. Renumbering of the Use Cases 2-6.
1.4	7/4/2011	GBO	Integration of RK's remarks.
1.5	29/4/2011	GBO	Chapter §2.3, Patient's Haematological Profile and Permanent Report added. Further discussion required.
1.6	26/5/2011	GBO	Permanent Report concept removed from Chapter §2.3 after discussion with Dr. Paul Courier, RK and JCD. Replaced by special Haematological Profile lab report and a reference to the new concept of Patient Summary (PS) .
1.7	16/6/2011	GBO	Correction in LAB-UC2 Lab Result Cancellation & Replacement - in step 6, main scenario: replaced "downloaded" by "viewed or downloaded". Other minor corrections.
2.0	27/6/2011	GBO	Validation in the LABO CoPil on 22/6/11 with one change in LAB-UC2 Lab Result Cancellation & Replacement (requested by EHL): Changed order of the return of the list of the actual viewers to the lab. Submission of replacement report is moved further down the workflow. Also corrected in the CoPil presentation "LABO-WP2-UseCasePresentationCOPIL20110622final.ppt"

¹ Use cases form roughly 25% - 30% of the future system's requirements. There are two more types of requirements, to be covered in separate documents called the **functional** and the **technical analysis**.

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§1 Introduction and Terminology

The LABO use cases in this document represent a contract between the future main users of the system, also called *stakeholders*, by explaining what is expected from each stakeholder and the system in order to work properly. They accurately describe, from the perspective of its users, the system's behaviour under various conditions and usage situations, and form therefore the basis of the system's functional description.

While use cases focus entirely on the user's point of view and his general interaction with the system, other types of analysis documents will focus more on the system itself, both from a functional and technical perspective.

The following general template will be used to present the different use cases:

ID:	CA-UCX	Name:	A short name
Short Description:	A one or two phrase summary description of the use case, stating its principal stakeholders and main purpose.		
Stakeholders & Interests:	Stakeholders:	Interests:	
	List of stakeholders and their motivations / interests in this use case	
Trigger event:	An event, which can be an action from another use case, and which triggers the actions and events of the current use case.		
Preconditions:	A list of conditions that needs to be fulfilled in order to make the use case applicable. Situations not fulfilling the preconditions are considered outside of the scope of the use case, and not covered by the specification.		
Main scenario:	Describes the normal, most likely flow of events and interactions that determine this use case. They are written down as an enumerated list of interactions, whereby the numbering suggests some timely order. However, interactions may also occur in parallel or with no predestined order.		
Alternatives:	A different flow of events in respect with the main scenario. If differences become too important, it should be considered to split the use case.		
Exceptions:	Exceptions represent failures of the system to perform normally. Contrary to the preconditions the exceptions lie within the scope of the use case and are therefore part of the specification.		
Extensions:	Extensions are the conditions under which the system performs a different behaviour. Extensions, as opposite to exceptions are considered normal behaviour.		
Remarks:	Additional annotations and remarks that are not covered by any other category.		
Related UCs:	A list of use cases related to this one.		

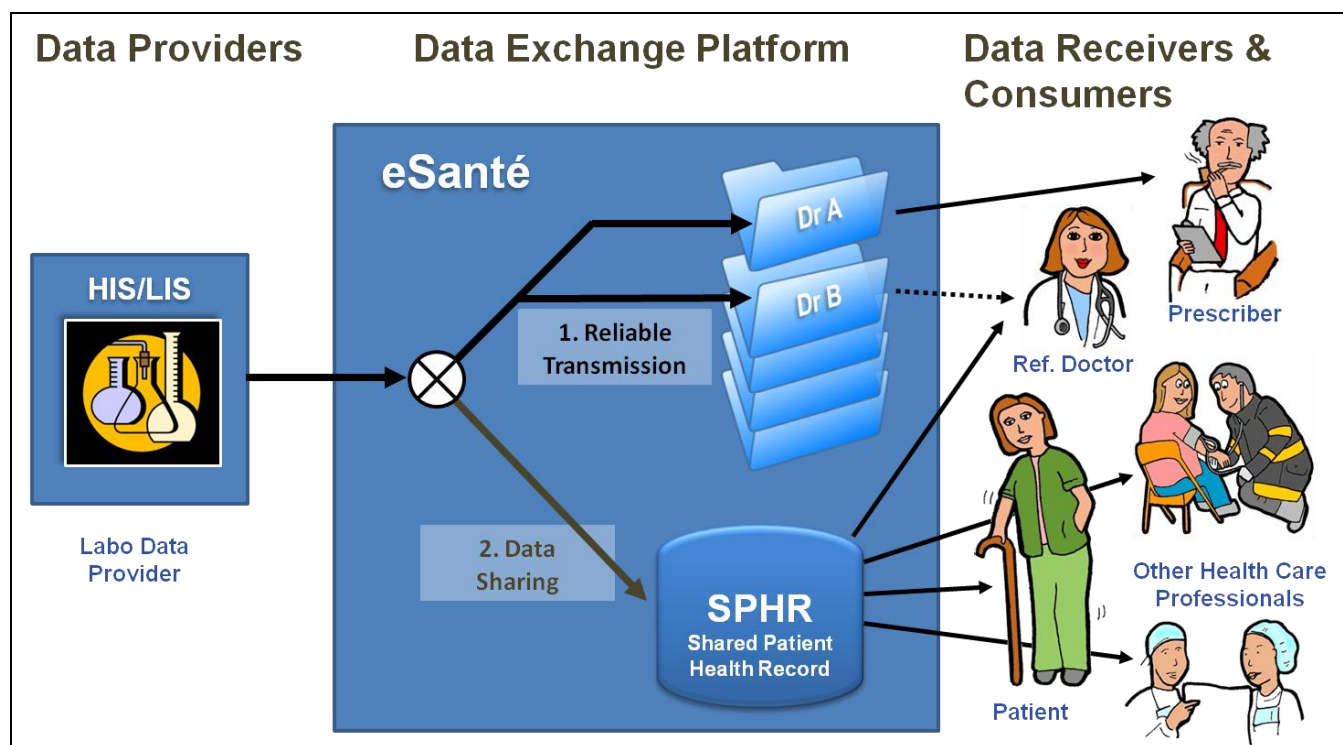
A glossary which defines the meaning of specific terms is added at the end of the document. [Hyperlinks](#) into the glossary are provided throughout the text whenever appropriate.

§2 Data Provider Use Cases

The first use case provides all LABO relevant data for [the eSanté Platform](#). All other use cases make, directly or indirectly, usage of data entered in the system through this use case. It is important to note that, depending on his [consent situation](#), a patient's medical data may

- only **transit over the platform**, in order to be delivered electronically to the receiving parties such as the [prescriber](#) and possibly the [reference doctor](#). Once downloaded by all receiving parties, the data will be deleted from the platform.² This is the case for patients who have not given or revoked their consent to have a [Shared Patient Health Record \(SPHR\)](#), or have no SPHR at all, e.g. foreigners or residents not being enrolled at all in the Luxemburgish health system. Because this transitional dataflow works for all kinds of patients we also refer to it as **Reliable Transmission**.
- be **permanently stored on the eSanté platform** in his SPHR if the patient has been enrolled in the eSanté platform, and if he has given his consent to have an SPHR. This is also referred to as **Data Sharing**.

The following diagram pictures the two different data exchange modes.



It should be noted that, depending on his [roles and privileges](#), the same health care professional can have access to a patient's data via both access methods: The reference doctor e.g. may have a permanent access to his patients SPHR while also receiving copies of all new results, but the view will be different:

- The **Reliable Transmission** delivers individual documents (such as lab results) to identified recipients (prescribers, reference doctor, ...) for all patients.
- The **Data Sharing** over the SPHR shows both new and historical documents for one selected patient at a time.

² There should also be a time limit for the receiving parties within which a document can be retrieved, based on the documents individual lifetime on the platform. When a document's lifetime is expired, it should be deleted permanently, even if not all recipients have downloaded it yet. Otherwise one single recipient who does not download the document would block its removal indefinitely.

§2.1 LAB-UC1 - Labo Data Provider

The detailed workflow for laboratory exams is likely to differ in details for the different laboratories, and especially between hospital and private labs. Therefore the following provider use case will not go into details about prescriptions, specimen collection, order placement & filling, test scheduling & execution, and report production & validation. Instead it will focus on the availability of test results that are already [clinically validated](#), which is precisely the status of results that is required for their transmission to the eSanté platform.³

Validated test results, also called *reports* (or « *comptes rendus* »), come in two variations:

- [Partial](#) - a subset of the results that have been ordered
- [Complete](#) - the whole set of ordered results

If all results are delivered at once there will be only one report, which is of course complete. Patients can only see complete reports in their SPHR, doctors receive and have access to both partial results and complete reports. Some labs send different [print or display versions](#) of the same report to patients and doctors. The doctor receives an annotated and commented version (e.g. highlighting abnormal values, adding some commentary text) while the patient receives the “raw”, uncommented version, in order to not alarm him. This is sometimes called an “interpretation”, but does not constitute a third type of lab document.

Data providers should check in their own LIS systems if the required information is available and distinguishable as partial or complete report, and also if different visualization models are available for patients and doctors, if this is wanted.

ID:	LAB-UC1	Name:	Labo Data Provider
Short Description:	Through the existing LIS system the laboratories and their personnel provide laboratory data in machine and human readable form to eSanté . The existing result delivery modes, such as print-outs sent by mail, FAX, on-line consultation over Web portals etc., will be maintained.		
Stakeholders & Interests:	Stakeholders:	Interests:	
	Patient	Wants his laboratory data being rapidly transmitted by electronic means and possibly stored in his electronic health record for long term reference.	
	Laboratory personnel	Wants to speed-up the transmission of their laboratory report to the data recipients and facilitate data sharing with patients and other health care professionals (HCP) .	
	Authorized data consumers , usually HCPs, such as the prescriber and the reference doctor .	Want to have fast electronic access to new laboratory results, as well as access to previous results, and an easy way of sharing this data with other colleagues.	
	Patient	Has a legal right to his own lab results.	
Trigger event:	A test result ordered at the laboratory is ready to be clinically validated by the responsible biologist.		
Preconditions:	The validating lab biologist is registered as a user with his local LIS system, which in turn is registered as a trusted node with the Santé platform.		

³ More detailed use cases about order placement, order filling and work order management can be found in the IHE profile “Laboratory Testing Workflow” (LTW), pp. 25-32 (http://www.ihe.net/Technical_Framework/upload/ihe_lab_TF_rel2_1-Vol-1_FT_2008-08-08.pdf), but are out of scope for the current project. The use cases presented in this document correspond to the XD-LAB profile (“Sharing Laboratory Reports”), pp. 68-73, in the same document.

<p>Main scenario:</p>	<ol style="list-style-type: none"> 1. The lab biologist clinically validates a test result, which represents a partial result or the complete report. 2. At that point the following information is transmitted to the eSanté platform <ul style="list-style-type: none"> • Patient identification information • Data recipient information (prescriber, 3rd party data recipients) • Data sender information (hospital, lab, LIS) • The clinically validated test result in an electronic format that is human-readable with an appropriate viewer software⁴ • Other meta-data required by the eSanté platform such as author, date and time, the list of test types contained in the report, visualization options for doctors, patient read blocking marker, an unlock code, abnormal results etc.⁵ <p>In response to a transmission the eSanté platform returns an acknowledge/failure message to confirm the status of the transaction.</p> 3. The data recipients who have subscribed to the notification service for lab results (use case LAB-UC6) receive notification messages shortly after the data transmission. 4. Patients do not have access to partial results over the eSanté platform, only to the final complete report. The doctors however may have a different visualization option, so that they could see partial reports. 5. The access to a report may be blocked by the lab so that the patient can't access it until the «<i>visite d'annonce</i>», in which the prescriber or any other authorized HCP explicitly unblocks it, usually after having explained the content to his patient in layman's terms. Alternatively the HCP can give the unlock code, added to the document by the data provider, to the patient, who can then unblock the document himself. If a report is not unblocked by a doctor within a certain delay after its submission eSanté unblocks it automatically after this delay.⁶ 6. The test results are also transmitted to the patient and all identified data recipients, such as the prescriber and other involved 3rd party HCPs, in the usual way (letter, fax, email, Web portal, ...).⁷
<p>Extension</p>	<p>Validation by electronic signature</p> <ol style="list-style-type: none"> 1.a.1. The responsible laboratory biologist validates the report (partial or complete) by signing it electronically in the LIS system. Given the large number of documents to be validated in average per day (>1000 for some labs) a bulk signing function for validating several documents in one single step should be provided by the LIS.⁸ 2.a.1. Same as point 2. of the main scenario, except for the 4th bullet which now reads (<u>changes underlined</u>): <ul style="list-style-type: none"> • The clinically validated test result in an electronic format that is human-readable with an appropriate viewer software, <u>and which has been digitally signed by the validating biologist</u>

⁴ Which exact electronic format(s) and associated reader software should be used will be determined in a later step of the analysis process, but it is highly likely to be HL7/CDA r2(Clinical Document Architecture), which allows for three levels of formatting: encapsulated PDF, lightly structured XML and deeply structured XML.

⁵ A more complete list needs to be determined in a later step of the analysis process.

⁶ This has to be done to guarantee a patient's final access to his lab results. Both partial and complete reports should be unblocked, even if partial ones are normally not visible to the patient.

⁷ The intend is that in the long run the electronic transmission and document sharing will replace paper and other "traditional" media, in the same way that email has largely replaced ordinary mail and FAX in today's modern business communications. Some labs already offer to patients and doctors a variety of on-line services such as email or SMS notification and Web-portals.

⁸ This requires that the LIS systems used in the Labs are able to digitally sign reports that are prepared in electronic format (PDF documents, XML files or parts thereof), and needs to be coordinated with the general security policy of the lab (and possibly the hospital). Another important question is whether the type of electronic signature used by the LIS qualifies as a legal signature in Luxemburg.

<p>Remarks:</p>	<ul style="list-style-type: none"> • The doctors in the GT LABO have declared that the notification mechanism will be of limited interest to them, as they are already today overwhelmed by emails that they do not have the time to read. There was a slightly higher interest for notifications if the report contains abnormal results. In general the notification for new lab reports may be more useful for patients than for doctors. We therefore keep this option in the specification, knowing that doctors probably won't use it a lot. • Point 4 and 5 of the main scenario are not really part of the provider use case, but belong rather to two the data viewer Use Cases. They are included here only to provide a better context of understanding. • The main scenario handles all necessary data input to the eSanté Platform through the lab's LIS, which transmits it automatically. This requires 2 things from the LIS: <ol style="list-style-type: none"> 1. All required data is available in the LIS (test results & meta-data). 2. All potential data recipients (prescriber, patient, 3rd party HCP) must have been entered in the LIS or otherwise be present in a way that allows their identification.⁹ • Whenever the patient identification information provided by the LIS is not sufficient to identify a patient uniquely, or if the patient is not registered with the platform, eSanté considers him as a new patient. As the consent situation is unclear at that moment his data will be treated in a similar way as known patient with no consent, meaning that the results are transmitted over the platform to the recipients, but not stored in the SPHR. • The use case extension "Validation by electronic signature" requires the validating biologists to sign the reports digitally, which is the legal digital equivalent of his hand signature. The digital signature has two functions: <ol style="list-style-type: none"> a) It legally identifies the signee b) It guaranties the integrity (no alteration) of the signed document. <p>A question remains: Who should sign electronically - the lab as an organisation, or the responsible biologist as a individual person?</p>
<p>Related UCs:</p>	<p>LAB-UC3 - Single Patient Data Viewing & Import LAB-UC4 - Patient Data Viewing LAB-UC5 - Reliable Data Transmission LAB-UC6 - Notification Subscription/Unsubscription</p>

⁹ While point 1 is expected to be satisfied, point 2 could require modifications in the LIS itself, at least to make sure that sufficient identification information for HCPs is available. A questionnaire and the following gap analysis conducted in the LABO project will give definite answers to those questions.

§2.2 LAB-UC2 - Lab Result Cancellation & Replacement

There are exceptional situations when a clinically validated and already published (or printed) report needs to be cancelled due to an error, and possibly be replaced by a new version.¹⁰ In most cases this occurs when the patient identification is faulty, e.g. assignment of the wrong patient during the order entry or even confusion of specimens. Much rarer are problems with the analysis itself. When the problem is detected each laboratory executes its own cancel-and-correct procedure, such as

- Validating and republishing (electronically) the correct result;
- Calling the ordering doctor by phone in order to inform him to get the correct result instead;
- Printing the correct report, signing it and sending someone to the ordering doctor to replace the wrong report with the correct one.

These internal procedures remain of course in place, but need to be mirrored to some degree in the eSanté platform, which represents a parallel publishing channel in addition to the laboratories' own. The following use case takes care of the above described situations.

ID:	LAB-UC2	Name:	Lab Result Cancellation & Replacement
Short Description:	The laboratory cancels an already published test result, or replaces it by a newer version. The cancelled / replaced report is marked as 'deprecated' and thereby made unavailable for viewing and downloading. Cancellation messages and notifications are sent to inform data recipients and consumers. The cancelling lab receives the list of all recipients that have already viewed or downloaded the report, so that it can undertake its own actions.		
Stakeholders & Interests:	Stakeholders:	Interests:	
	Lab biologist	Wants to cancel a previously transmitted result, and possibly replace it with a new version.	
Trigger event:	The biologist decides to cancel or to replace a submitted report.		
Preconditions:	The validating lab biologist is registered as a user with his local LIS system, which in turn is registered as a trusted node with the Santé platform.		
Main scenario:	<ol style="list-style-type: none"> 1. In the lab's LIS the biologist requests the cancellation of an already submitted result. He can also join a new report that replaces the cancelled one. Optionally a short text notice should be provided, intended to explain the reason for the cancellation/replacement.¹¹ 2. The LIS sends the cancel request to the eSanté platform. 3. If the original lab result has been stored in the patients SPHR the system marks the original report as 'deprecated'. Deprecated documents can no longer be viewed by patients or doctors. 4. If the original lab result has been sent directly to one or more recipients (reliable transmission) two cases can occur:¹² <ol style="list-style-type: none"> 4.1. The report has not yet been downloaded & decrypted → Silently remove the cancelled report. 		

¹⁰ This should not be confused with the successive building up of partial reports to the complete report, which is the normal process. Even if a later report includes the data of the previous ones they do not cancel or replace those previous reports. Rather they should be seen as a kind of complement or addendum.

¹¹ This assumes that the LIS has an own cancel/replace function that corresponds largely to the eSanté cancel/replace function described in this use case. If this is not the case, eSanté will have to provide a user interface to allow the biologist to perform this function independently from the LIS, which would be rather cumbersome.

¹² Note that both cases can occur in parallel if there is more than one recipient: Dr. A has not yet downloaded the report, but Dr. B already has.

	<p>4.2. The report has already been downloaded & decrypted → A cancellation message is placed in the recipient's Incoming Folder.</p> <p>5. All data consumers who have subscribed to cancel events on the eSanté notification service will receive a notification with a cancellation notice.¹³</p> <p>6. The system returns a cancellation confirmation to the requestor. The list of all recipients who had already viewed or downloaded the original report is returned to the cancelling lab.</p> <p>7. Optionally the LIS sends a replacement report to eSanté which takes the place of the now deprecated report in the SPHR. The replacement report is also placed in the recipient's Incoming Folder.</p> <p>8. The lab contacts all those recipients that had already downloaded the document by its own means (phone, fax, personal visit, ...).</p>
Exceptions:	<p>1.a. Connection and identification problems (see LAB-UC3, exception 1.a.)</p> <p>4.a. Failure to cancel If the cancellation / replacement operation fails, the system returns a failure message with further information about the causes (insufficient privileges, document not found, ...)</p>
Remarks:	<ul style="list-style-type: none"> • This use case can be used to cover the following situations: <ul style="list-style-type: none"> ○ Replacement of an erroneous report for the same patient with a new, corrected version of this report. ○ Cancelling a submitted report with a wrong patient, and sending it to the right patient. ○ Cancelling a report without any replacement. This includes the notification of the recipients / consumers. • The list of the users that have already downloaded the cancelled/replaced report must be somehow processed by the lab's LIS, otherwise this special feature of the cancel/replace function will not be useful to the lab. Right now it is unclear if this is technically possible, because it depends on the LIS' capability to integrate the feature. • Notifications and Messages: In the above text we distinguish between notifications and messages. Although similar in function they are delivered by two completely different and independent mechanisms of the platform: <ul style="list-style-type: none"> ○ Notifications are events that the user has to subscribe to in order to receive them (see LAB-UC6 - Notification Subscription/Unsubscription). He also needs to provide a valid email address to get them delivered. Notifications can be received by all users, i.e. patients and HCPs. ○ Messages are special documents that are reliably transmitted and placed in a recipient's Incoming Folder. They are downloaded together with all other documents destined for a HCP (see LAB-UC5 Reliable Data Transmission). Messages can be received only by HCP through reliable transmission. <p>The sending of a message for a cancelled or replaced report (point 4.1) is not a precondition for sending notifications. All users who have subscribed to a cancel / replacement notification event will receive such a notification, even in case of a silent replacement.</p>
Related UCs:	<p>LAB-UC1 - Labo Data Provider LAB-UC6 - Notification Subscription/Unsubscription</p>

¹³ See remark at the end of the use case for the distinction between cancellation message and notice.

§2.3 Patient's Haematological Profile and the Patient Summary

The Luxemburgish Red Cross systematically runs a series of haematological tests for each blood donation in order to guaranty the quality and safety of all blood donations that it collects. Beside the detection of pathological events (viral hepatitis, AIDS, parvovirus B19, ...), which will be included in a patient's SPHR after he is transferred to a hospital or a general physician, there are other, non-pathological haematology results such as the determination of different blood groups (system AB0, Rhesus, Kell) and anti-bodies (allo-antibodies). The genetically determined blood group systems remain mostly stable over a patient's lifetime, except for the rare cases of multiple blood transfusions and bone mark transplantations. Allo-antibodies, however, are acquired trough exposure, e.g. at birth, during a blood transfusion or an organ transplantations, and can therefore change over time.

These indicators are of particular importance for a patient in case of an emergency blood transfer, and should therefore be integrated, as prominent information in the patient's [SPHR](#), if known. The haematological results coming from the Red Cross, but also from other labs, should be submitted to the patient's SPHR in form of a special lab report.

Reliable Transmission can, but need not necessarily happen in this situation. If the blood group determination has been ordered by a surgeon in a hospital the result could be addressed to this surgeon, although he has probably easier and faster means to get the results directly from the hospital lab. However, if blood group determination is a side-product of a blood donation at the Red Cross there will be no prescriber. In any case the blood group determination should go into the patient's SPHR, where it may be re-used in the → [Patient Summary \(PS\)](#).

In the case of a blood group determination a specific type of lab report, the **Haematological Profile**, should be submitted. It can contain the following results:

- Blood groupe AB0
- Rhesus factor
- Kell group
- List of detected allo-antibodies

For submitting this report to eSanté the LAB-UC1 - Labo Data Provider use case fully applies.

§3 Data Consumer/Receiver Use Cases

§3.1 Overview

There are 3 [data consumers/receiver](#) use cases. All of them provide scenarios to access a patient's medical data stored in the [SPHR](#), or transmitted over the eSanté platform. The difference between them is that they either address different groups of data consumers/recipients, or give access to different sets of data.

- **LAB-UC3 - Single Patient Data Viewing & Import** is the most basic consumer use case. It is [patient centric](#), i.e. data can only be searched for one patient at a time. The person who searches the data is a [HCP](#), who can e.g. be the [reference doctor](#), the [prescriber](#), or any other health care professional authorized to see the patient's data. The patient's available and accessible data is shown, possibly limited by some yet to be defined filter mechanism, and ordered according to some ordering criteria.
- **LAB-UC4 - Patient Data Viewing** is a special case of the previous use case. In this scenario the viewer is the patient himself, and he is allowed to see only his own medical data, except in the case that it still may be [blocked](#) until an authorized HCP has unblocked it.
- **LAB-UC5 - Reliable Data Transmission** is a [receiver centric](#) use case that allows to access in one step several data sets belonging to different patients. Here the receiving parties, mostly prescribers, can quickly download and then visualize results for tests that have been sent to them over the platform. This kind of "combined download" is comparable to the functioning of today's HealthNet Labo service, but fully integrated into the eSanté platform, and more convenient to use.

The following table summarizes the major differences and similarities between the viewer use cases.

Use Case	View	Which patients?	Which data?	View /download
LAB-UC3 - Single Patient Data Viewing & Import	Patient centric	Any one patient	All results the viewer has access to.	View, download is optional
LAB-UC4 - Patient Data Viewing	Patient centric	The patient himself	All unblocked tests	View, download is optional
LAB-UC5 - Reliable Data Transmission	Receiver centric	All patients with new results	Received results	First download, then view ¹⁴

§3.2 LAB-UC3 - Single Patient Data Viewing & Import

ID:	LAB-UC3	Name:	Single Patient Data Viewing & Import
Short Description:	Reference Doctors & other authorized HCPs view & possibly import laboratory test results of one single patient (patient centric view).		
Stakeholders & Interests:	Stakeholders:	Interests:	
	Authorized data consumers, i.e. prescribers , reference doctor & other authorized HCPs)	Want to consult and possibly download lab test results for one specific patient.	
	Data providing Labs	Want to control the accessibility and quality of the rendering and the visualization of the	

¹⁴ See section §3.5, Web Viewers and Patient Management Software Integration, for more detailed info.

	reports they have submitted.
Trigger event:	The data consumer decides to consult a patient's SPHR , possibly after having been notified by email.
Preconditions:	<ul style="list-style-type: none"> The data consumer is registered with the eSanté platform as a user. The data consumer has been properly authorized to view all or parts of a patient's SPHR. The patient's consent for storing lab results in the SPHR on the eSanté platform is given.
Main scenario:	<ol style="list-style-type: none"> The consumer authenticates himself to the eSanté platform. The consumer connects to eSanté's SPHR database. The consumer enters demographic identification information for a patient whose laboratory results he wants to see. If the patient can be uniquely identified the system presents the set of data entries for this patient, which the consumer is allowed to see over a secure data exchange channel.¹⁵ The consumer selects individual data entries, and the system shows the corresponding data to the consumer. A partial result is clearly distinguishable from a complete report. So are stationary and ambulatory reports. The user can also search for specific types of tests. Optionally the consumer downloads the selected data and stores it on his computer, either in form of a file, or by automatically adding it to the appropriate patient record in his own Patient Management System (PMS).¹⁶
Exceptions:	<p>1.a. Connection and Identification Problems</p> <ol style="list-style-type: none"> 1.a.1. In case of technical unavailability of the eSanté platform the system informs the user that this is the case and indicates how to proceed (please try later, call hotline etc.), and the use case ends. 1.a.2. If the identification of the user fails, he is denied access, and the use case ends. <p>4.a. Failed Patient Identification</p> <p>If the patient identification information was insufficient to identify a patient uniquely, the system informs the user and gives hints on how to improve the search criteria. The use case then ends, or continues at step 3 if the user wishes so.</p>
Extensions:	<p>Read-block Removal</p> <ol style="list-style-type: none"> 7.a.1. If the lab has blocked the report for patient reading an authorized HCP can remove this block. From now on the patient can read the report. 7.a.2. The patient can also unblock the report himself if his doctor has given him a special unblock code. This code has been generated by the LIS and is printed on the written report that was sent to the doctor, as well as on all electronic versions in the system. This feature allows the patient to do the unblocking himself in cases where his doctor does not use the eSanté platform at all.
Remarks:	<ul style="list-style-type: none"> We assume that any HCP having access to a patient's SPHR can remove the read block from a document, i.e. the reference doctor and any other doctor

¹⁵ The communication channel used to transfer any patient data to the consumer is securely encrypted by eSanté, and decrypted on the consumer's side. This operation runs in the background, and is therefore transparent for the user.

¹⁶ Importing patient data directly into a doctor's patient management system requires that such a system be extended with an access function that acts as a connector to the eSanté platform. The functional specification of the eSanté platform will provide the necessary [APIs](#) for such an integration, but not the functionality itself. See section §3.5 'Web Viewers and Patient Management Software Integration', third schema, for more details.

	<p>who received access by means of patient consent, patient referral etc.</p> <ul style="list-style-type: none"> Emergency access to a patient's SPHR still needs further clarification. Points to consider are: <ul style="list-style-type: none"> Minimal demographic data required for patient identification Special justifications required for the doctor, or special roles that allow emergency access (could be time-limited!) Logging Notification of patient and other involved persons
Related UC:	LAB-UC1 - Labo Data Provider

S3.3 LAB-UC4 - Patient Data Viewing

ID:	LAB-UC4	Name:	Patient Data Viewing
Short Description:	The patient, after having been duly identified by the system, can view and possibly download his own laboratory results on the eSanté platform.		
Stakeholders & Interests:	Stakeholders:	Interests:	
	Patient	Can consult his lab test results on-line, and benefits from the result history kept in his SPHR .	
Trigger event:	The patient wants to consult his laboratory data in his SPHR.		
Preconditions:	<ul style="list-style-type: none"> The patient is registered with the eSanté platform as a user. The Patient has given consent that his laboratory data can be stored on the eSanté platform.¹⁷ 		
Main scenario:	<ol style="list-style-type: none"> The patient authenticates himself to the eSanté platform by means of a secure method that identifies him legally¹⁸. The patient connects to eSanté's SPHR database. The patient selects, filters and displays his own available lab results over a secure data exchange channel¹⁹. He only has access to complete reports, even if there may also be partial reports which a HCP can see. Some reports may have been blocked for patient reading on the prescriber's explicit demand, and therefore cannot be read by the patient, even if he sees their presence in his SPHR. Such reports can be un-blocked by an authorized doctor, usually during or after the "vistite d'annonce". Optionally the patient downloads the selected data and stores it on his computer in a file. 		
Extensions:	3.a. Unblocking by patient using the unblock code If the doctor has given the patient the unblock code for a blocked report the patient can use it to unblock this particular report.		
	3.b. Before displaying the report the system instructs the patient to consult his doctor for a professional interpretation of the results.		
Exceptions:	1.a. Connection and identification problems (see LAB-UC3, exception 1.a.)		
Remarks:	<ul style="list-style-type: none"> The question has been raised by the general physicians if the patient should in general be allowed to access his SPHR without the assistance of a doctor. 		

¹⁷ Without patient consent there is no SPHR to access to.

¹⁸ Such as LuxTrust.

¹⁹ Before displaying the results are also downloaded and decrypted, but those steps run automatically in the background and are transparent for the patient.

	<p>Furthermore it was argued that such easy and unlimited access could lead to a situation where patients will no longer consult their physicians, and rather interpret results themselves, which could be dangerous for them.</p> <p>To avoid this, the eSanté platform should incite patients to seek the council of a qualified HCP who should interpret the results for them.</p>
Related UC:	LAB-UC1 - Labo Data Provider

§3.4 LAB-UC5 - Reliable Data Transmission

The following receiver use case is different from the two previous ones, LAB-UC3 - Single Patient Data Viewing & Import and LAB-UC4 - Patient Data Viewing, mainly because it is [receiver centric](#) instead of [patient centric](#). As a consequence the focus is on the data recipient, not on the patient whose data is to be viewed. Also this use case delivers lab results and other types of documents to known recipients for all patients, with or without an [SPHR](#), and it works even if the patient could not be identified in the eSanté platform.

It therefore represents a reliable data transmission channel for all medical documents.

ID:	LAB-UC5	Name:	Reliable Data Transmission
Short Description:	Recipients of laboratory test results download and then view new data that has been sent to them.		
Stakeholders & Interests:	Stakeholders:	Interests:	
	Identified data recipients (prescribers & other authorized HCPs)	Want to consult laboratory results for tests sent to them, as soon as they are available.	
Trigger event:	(optional) The data recipient is notified that new laboratory data are available for his appreciation.		
Preconditions:	The data recipient is registered with the eSanté platform as a user.		
Main scenario:	<ol style="list-style-type: none"> 1. The recipient authenticates himself to the eSanté platform. 2. The recipient connects to the eSanté Platform. 3. The system shows the recipient a list with new medical reports that have been sent to him. Only results not yet downloaded by him are shown.²⁰ 4. The recipient selects a subset from the list of data entries and downloads them in one single step ('combined download')²¹. The system automatically marks the downloaded results as read, and from now on they will no longer be presented to him for download. 5. The system decrypts the downloaded results locally on the recipient's side.²² 6. Immediate Data Removal If the patient has no SPHR due to his consent situation, or if he couldn't be properly identified by eSanté, the patient's medical data is permanently removed from the eSanté platform. Only log traces for auditing purposes, not visible for normal users, remain in the system²³. The removal happens immediately after all receiving parties have acknowledged the successful download and decryption of the data on the recipient's side. 7. The recipient views the downloaded data one-by-one, and optionally adds them 		

²⁰ At that point the recipient cannot see to which patient a result belongs. This is because the data and patient information are still encrypted and not available to the system, but he can see the date, source and type of each data entry.

²¹ A 'select all' function will be provided for convenience.

²² Now it becomes apparent to which patient a result belongs.

²³ We assume that there is a logging mechanism tracing all data movements and accesses, but the description of this mechanism is out-of-scope for the present document.

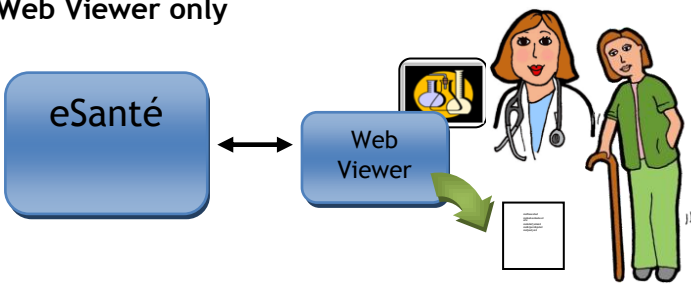
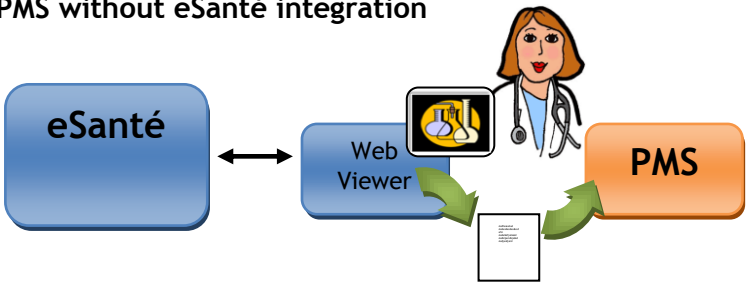
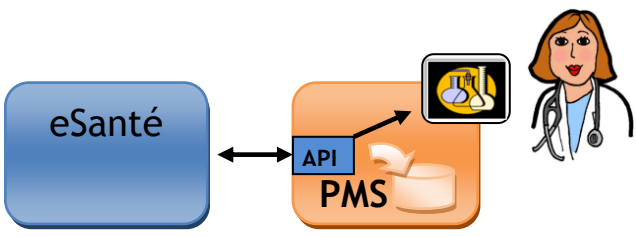
	to the patients' records in his own PMS .
Exceptions:	1.a. Connection and identification problems (see LAB-UC3, exception 1.a.)
Alternatives:	6.a. Document removal after exceeding an expiry date In order to avoid that a missing or unsuccessful download from any one of the data recipients would keep a patient's data forever on the platform against the patient's explicit wishes and the platform's policies, every document has a "transmission expiry date". Documents exceeding this date will be automatically deleted from the platform, even if some of the recipients haven't yet downloaded them.
Extension:	Unblock Code 7.a. When viewing the document the HCP has also access to the unblock code that has been added by the data provider. The doctor can give this code to his patient so that the latter can unblock the report himself, without direct intervention of the doctor.
Remarks:	<ul style="list-style-type: none"> The present use case differs from the previous two viewer use cases, LAB-UC3 and LAB-UC4, in several ways. First it is consumer centric, meaning that data is directly delivered to clearly identified recipients. Secondly the patient to whom the data belongs may not be uniquely identifiable in terms of the eSanté platform, such as in cases of an unconscious accident victim with no credentials. Thirdly the patient, even if uniquely identifiable in eSanté, may not wish to have a permanent SPHR (no consent given). In such cases the data is removed after a certain period of time from the platform according to the above specified rules. It should also be noted that in the normal situation (patient identifiable and consent given) this use case is not a replacement but an additional delivery path. Only if patient identification fails or there is no SPHR it is the only possible delivery way of patient data to the recipients. This use case therefore represents a reliable transfer mechanism that guaranties data delivery to the identified recipients, and should be the preferred way for a doctor to receive new results for his prescriptions. Steps 3. and 4. could be merged into one download-all-available-data step, but given the fact that there may be a large number of different results which are long to download it is prudent to allow the user to make a pre-selection first, e.g. only laboratory reports from one single source etc. It should also be possible to interrupt a combined download operation if it takes too long, having the completed downloads marked as 'read', and leaving the untouched ones on the eSanté platform for later download. Another possibility would be the automatic download of all data in the background, with a pop-up message informing the user about the end of the download.²⁴
Related use Cases:	LAB-UC1 - Labo Data Provider LAB-UC6 - Notification Subscription/Unsubscription

²⁴ A mix of both functions is possible too: manual start, then download in the background, signalling the end by a popup message.

§3.5 Web Viewers and Patient Management Software Integration

From the start the eSanté platform has to provide the technical means for every authorized data viewer/recipient to visualize and possibly download accessible patient data. The best solutions for doctors would be to have a fully integrated access to eSanté within their own [Patient Management System \(PMS\)](#). Doctors without PMS, or with a PMS that is not yet integrated, are given access over a Web Browser. The same holds for patients.

Three situations will be covered as front-end solutions to the eSanté platform.

<p>Web Viewer only</p>  <p>The diagram shows a blue box labeled 'eSanté' connected by a double-headed arrow to another blue box labeled 'Web Viewer'. To the right of the Web Viewer, a doctor in a white coat and a patient in green scrubs are shown. A green arrow points from the Web Viewer to a document icon, indicating data access.</p>	<p>Patients and doctors without a PMS can view and possibly download patient data from the eSanté platform through a Web viewer interface.</p>
<p>PMS without eSanté integration</p>  <p>The diagram shows 'eSanté' connected to 'Web Viewer'. A doctor is shown with a tablet displaying the Web Viewer interface. To the right is an orange box labeled 'PMS'. A green arrow points from the Web Viewer to the PMS, and another green arrow points from the PMS to a document icon, showing manual data transfer.</p>	<p>Doctors with a PMS that is not integrated with the eSanté platform can view and possibly download patient data through eSanté's Web Viewer interface. If they want to keep a local copy they need to upload the files manually into their own PMS, where they attach them manually to the corresponding patient records.</p>
<p>PMS with eSanté integration</p>  <p>The diagram shows 'eSanté' connected to a PMS box via a blue box labeled 'API'. A doctor is shown with a tablet displaying the PMS interface, which is directly connected to eSanté.</p>	<p>Doctors with eSanté integrated PMS can view and optionally download patient data directly in their own software, without manually downloading/uploading it with the Web viewer. An API is provided by eSanté to allow the software vendors to integrate the required eSanté functions, i.e. viewing & downloading.²⁵</p>

The viewer use cases described in section §2 are independent from the choice of the viewer software, which means that they should work with both the Web-Interface and the integrated PMS. The level of integration and additional eSanté functionality that the PMS will provide depends largely on the various software vendors. However, the API provided by the eSanté platform must guarantee that the functions required by the viewer use cases can be implemented.

²⁵ The very same API could also be used in HIS/LIS systems, e.g. in a hospital where the patient is treated stationary, to gain access to a patient's lab data, and in general by all data providing labs, so that they can control the availability and visualisation of the reports they have submitted.

§4 Other Use Cases

Chapters §2 and §2 described the core of the LABO use cases, i.e. data providers and consumers. The current chapter rounds up the LABO profile by providing a few supporting use cases, such as Lab result cancelling and notification management.

§4.1 LAB-UC6 - Notification Subscription/Unsubscription

Although presented as one single use case, this is actually a collection of two closely related use cases which show how a user of the eSanté Platform can subscribe to and unsubscribe from a notification service. This service allows a user to receive messages about the arrival of new laboratory test results he has access to, and other events such as cancelling and replacement of reports.

ID:	LAB-UC6	Name:	Notification Subscription/Unsubscription
Short Description:	Patients, doctors and in general any person participating in the eSanté platform can subscribe to be notified when new laboratory results have been sent to them and are now available in the eSanté Platform.		
Stakeholders & Interests:	Stakeholders:	Interests:	
	Patients, doctors and other registered users of the eSanté platform	Want to be informed when new test results they have ordered are available on the eSanté Platform for download.	
Trigger event:	The user decides to subscribe to the laboratory test notification service.		
Preconditions:	The user is registered as a user in the eSanté platform .		
Main scenario:	<ol style="list-style-type: none"> 1. The user authenticates himself to the eSanté platform. 2. The user connects to the notification subsystem of the eSanté Platform. 3. The user subscribes to the notification service for lab result related events, and specifies the email delivery address. Events of interest could be the availability of any new report, a new report with abnormal results, cancelling, replacement of reports etc. 4. The user confirms his choice and the system creates a laboratory test notification subscription for him. 5. The system sends a subscription confirmation to the user at the specified email address. The email message contains a URL that the user has to follow in order to activate and confirm his subscription. 6. The user follows the activation link and activates his subscription. He thereby also validates implicitly his email address. From now on, the notification service sends messages to the user informing him about events to which he has subscribed, as soon as they occur on the eSanté platform.²⁶ 		
Exceptions:	1.a. Connection and identification problems (see LAB-UC3, exception 1.a.)		
	6.a. Delivery failure If a message delivery encounters a failure the system logs this fact and schedules a limited number of retrials at a later time. If all of them continue to fail the notification subscription is automatically cancelled, without further notification to the user.		
Extension:	Un-subscription		

²⁶ Although not of relevance here, it should be mentioned that the name of patients or any specific medical information concerning them should never be mentioned in the notification messages, as this is confidential information, which should not travel over unsecure email channels.

	<p>Preconditions: The stakeholder is a user to the eSanté Platform notification service</p> <ol style="list-style-type: none"> 1. The user authenticates himself to the eSanté platform. 2. The user connects to the notification subsystem of the eSanté Platform. 3. The user to the un-subscribes himself from the laboratory result notification service. 4. The user confirms his choice and the system cancels his laboratory test notification subscription. 5. The system sends a un-subscription confirmation message to the former subscriber. This email message contains a link that the user has to activate in order to confirm his un-subscription. 6. From now on the former subscriber receives no more notification messages related to laboratory data on the eSanté platform.
<p>Related UCs:</p>	<p>LAB-UC1 - Labo Data Provider LAB-UC2 - Lab Result Cancellation & Replacement LAB-UC5 - Reliable Data Transmission</p>

§5 Additional Use Case Candidates

The following list of use case candidates should be considered in order to complete the whole eSanté system and make it more robust and functional. Most of them are not specific to the LABO project and apply in general to the eSanté platform.

Here we mention a few of them briefly, without further elaboration. Some of them have a strong relation with [Patient Consent Management](#), which should be tackled before elaborating these use cases.

- **Data Provider: Summary report from Hospital at discharge time.** At discharge time, a hospital physician selects the most significant reports produced by various facilities, including lab reports, and submits these reports to eSanté. Such reports are not a current practice in Luxembourg, but could occasionally be asked for by a doctor. In this case they could be handled like any other lab report ordered by a prescriber.
- **Data Provider: Patient adds data** and information in his possession about his own health, as he would do in a Personal Health Record (PHR). These patient entries should be clearly distinguishable from clinical results and entries from HCP.
- **Data provider: Cumulative lab reports.** A healthcare institution produces a cumulative report of all laboratory tests performed for the patient during an encounter. This cumulative report aggregates the test results related to one or more order groups, over a period of time.
Remark: Cumulative reports are not a current practice in Luxemburgish labs. They may occur occasionally on a physician's explicit demand to a lab, which will assemble and submit them based on their own data. Cumulative reports are not compiled by the eSanté platform, and can be handled like normal reports submitted by labs.
- **Data Viewer: Emergency access to a patient's SPHR.**
Remark: Out of scope for the current LABO Use Cases, but should definitively be considered in the larger eSanté project.
- **Data Viewer: Access to a patient's health record by proxy** (children & parents, legally appointed guardians, ...).
Remark: Out of scope for the current LABO Use Cases, but should definitively be considered in the larger eSanté project → [Patient Consent Management](#)

- Other: Regular replacement for the reference doctor during vacation or illness.
- Other: Patient notification in case of ordinary and extraordinary access to his health record.
- Other: A detailed model of [Patient Consent Management](#), including issues such as appointing the reference doctor, proxy assignment etc.

§6 Glossary of Terms

Wherever [hyperlinks](#) are provided in the text you can jump directly to the glossary entry with a simple click in the PDF document, or using Control + LeftClick in MS-Word. Alt + ← brings you back to the starting position.

Term	Description
3rd Party Data Viewer	Any person different from the patient, the prescriber and the reference doctor . Examples are: <ul style="list-style-type: none"> • another general physician or specialist chosen by the patient or the prescriber • authorized medical emergency personnel
Access rights, Privileges, Roles	Also called <i>privileges</i> . Privileges are commonly grouped together into <i>roles</i> , to facilitate their assignment to individual users. They define which user has access to what data. Access can furthermore be refined in different types such as read (= view), write (= create, delete) modify, and so on. <p>Examples:</p> <ul style="list-style-type: none"> • Prescribers can view and copy data for tests they have prescribed. • Laboratories can create, view, modify and delete their own laboratory reports. • Patients can view the reports of their own tests, but only after the prescriber or another authorized doctor, such as the reference doctor, has unblocked them. <p>Due to the lack of a proper patient consent management model at the time of writing of this document no specific roles and privileges can be given here.</p>
API	An Application Programming Interface (API) is an interface implemented by a software program which enables it to interact with other software. It makes possible the interaction between different software programs similar to the way the user interface allows interaction between humans and computers. ²⁷ <p>In classic programming an API is often delivered in form of a SW library for a target system, but the API can also take the form of a protocol for data transmission associated with a data format specification. In this case, e.g. through use of Web services, the API does not require any physical programming component such a library.</p>
Authentication	The act by which a physical person identifies him/herself to a computer system in order to gain entry into the system and access to its data. This is usually accomplished by using a login name and password, or more likely in this context, by using a secure token provided with a strong authentication method such as LuxTrust.
Blocked data, Read-block, Unblock code	Doctors may advice a laboratory on the prescription not to send the result to the patient, or at least to delay it, because it may contain disturbing news for him. For such cases the report sent to the eSanté can be marked as “blocked” by the laboratory, meaning blocked for patient access . It stays blocked until the prescriber , the reference doctor or any other authorized user removes the block, usually during the so called « <i>viste d’annonce</i> ». After that the patient has permanent access to the report.

²⁷ Definition from the Wikipedia, http://en.wikipedia.org/wiki/Application_programming_interface.

Term	Description
	The patient himself can also remove this read-block if he has been given the specific unblock code that the doctor can see on his versions of the report. Only data providers can put read-blocks on a patient's document. The HCPs can remove it, but cannot put a block on a document which they have not provided. ²⁸
Data consumers, Data recipients	As opposed to data providers, the consumers / recipients are on the receiving side of the data flow. In the eSanté platform data consumers are securely identified physical persons who have access to patient data, such as prescribing physicians , reference doctors , and other 3rd party data consumers . Patients are a special case because the identification process in the eSanté platform is different for them, and they are therefore always called 'patients', rather than data consumers. "Data recipient" is essentially an equivalent term to "data consumer", but is preferred in transfer use cases, where medical data is explicitly "send" to a limited number of known recipients. The distinction is done to emphasize the transient character of the data transmission channel.
Data receiver centric View	This term means that the data consumer is the pivotal point from which patient data is searched for. More specifically it means that the system shows data which have been explicitly sent to the recipient, and which may belong to any number of different patients. E.g. a prescriber can see all results of tests he has prescribed. This is in contrast to the patient centric view , where a user of the system can search for all accessible data for one given patient.
eSanté platform	The overall IT system that delivers the services and functions described in this series of use cases. Its main purpose is to store medical data related to patients in the Luxemburgish health care system, and to facilitate the secure and controlled exchange of data among its different actors. Beside data storage and transfer services the eSanté platform will provide other related services such as a Notification Service , the Patient Consent Management Service etc.
Health Care Professional Software (HCP-SW)	Software systems that are used by HCPs in order to conduct and manage their patients and work. Examples are <ul style="list-style-type: none"> • Medical cabinet software, • HIS/RIS/PACs systems, • Medical device software for monitoring patients • ...
Health Care Professionals (HCP)	Professionals that are working in the health care sector, such as doctors, nurses, medical assistants, Samu, etc. Depending on the role they play in a use case they are sometimes referred to as reference doctor , prescriber , laboratory, specialist, data consumers , data recipients , 3rd party data consumers , etc. All medical data providers are also HCPs, i.e. Labs, radiology departments etc. By default they have access to all data they have submitted.
Health Care Provider	In order to be able to use the system a health care professional has to be registered in the eSanté platform as a regular user. The minimal set of

²⁸ In future extensions of the eSanté platform the doctors may become themselves data providers, and thus be allowed to put read-blocks on the documents they have provided.

Term	Description
Identification	<p>information to identify uniquely a health care professional has still to be defined, but the following elements are good candidates :</p> <ul style="list-style-type: none"> • CNS-number • Social security number (“matricule”) • Name and surname • Medical specialty
Laboratory data, Partial results, Complete report	<p>Refers to laboratory test results, for which we distinguish 2 types</p> <ul style="list-style-type: none"> • Partial results - a subset of the results that have been ordered • Complete report - the whole set of ordered results <p>Often a prescriber orders a series of tests in relation with a certain clinical situation of his patient. The lab breaks down the entire order into individual tests. Depending on the nature of the tests and the lab’s internal workflow these results may become available at different moments in time, and therefore be published or sent out to the prescriber in more than one report, as so called <i>partial results or reports</i>. After the last test is done the lab assembles all partial results into a <i>complete report</i>.</p> <p>All partial results build up to the final complete report. Example: a test order is split into 3 parts: A, B and C. The 1st report contains test results A, the 2nd A + B, and the 3rd (= complete report) contains results A + B + C.</p> <p>It is current practice that patients receive only complete reports, while doctors get both partial and complete reports.</p> <p>Other information about the report such as the date of creation, a subject/title, the type of tests, the name of the validating biologist etc. is called <u>meta information</u>.</p>
LIS	<p>A Laboratory Information System (LIS) is a class of software that receives, processes, and stores information generated by medical laboratory processes. These systems often must interface with instruments and other information systems such as Hospital Information Systems (HIS).</p> <p>Most Luxemburgish laboratories use GLIMPS (<u>G</u>eneral <u>L</u>aboratory <u>I</u>nfor<u>M</u>ation <u>S</u>ystem), from the Belgian SW editor MIPS. The same company also provides the Laboratory Web visualization solution Cyberlab.</p>
Meta-Data	<p>Or <i>Meta-Information</i>. The system offers two kinds of information: actual <u>laboratory data</u> (appointments, reports, images), and meta-data, e.g. date of creation, label, modality, short description, author, etc. Typically a user will first see the meta-information before accessing the data itself (the <i>content</i>), e.g. in form of a summary line in the result list of a research.</p>
Notification Service	<p>Sub-system of the <u>eSanté platform</u> that can be used to subscribe / unsubscribe to a notification service. This service automatically generates messages at specific events, such as the availability of new laboratory test data, or access to a patient’s medical record.</p>
Patient Centric View	<p>This means that the patient is the pivotal point from which patient data is searched for. More specifically it means that one search operation can only return data for one given patient. This is in contrast to the <u>receiver centric view</u>, where a data recipient such as the <u>prescriber</u> can search for results he is the recipient of, no matter for which patient.</p>
Patient	<p>Or shortly Consent Management. A system of roles and rules that allows a</p>

Term	Description
Consent Management	<p>patient to define the access conditions to his SPHR. Wikipedia defines it as:</p> <ol style="list-style-type: none"> 1. Enables consumers to affirm their participation in eHealth initiatives in cases where participation cannot or should not be implied or assumed. 2. Enables consumers to establish privacy preferences / policies to direct who shall have access to their electronic personal/protected health information (PHI), for what purpose and under what circumstances. 3. Supports the dynamic creation, management and subsequent enforcement of consumer, organizational and jurisdictional privacy policies through access control mechanisms.
Patient identification information, Master Patient Index	<p>Patients are identified by the <i>Master Patient Index</i> of the eSanté platform. This is done by providing a set of info attributes such as the national Social Security Number (SSN), demographic information such as name(s), address(es), age, sex etc.</p> <p>The Master Patient Index then tries to find a unique match for the patient and after an additional <i>pseudonymisation</i> step, done by the TTP, returns a patient pseudonym, which allows to find the patient's SPHR on the eSanté platform.²⁹</p>
Patient Summary (PS)	<p>The Patient Summary concept hasn't been integrated into the eSanté platform, yet. Its detailed description should become the subject of a different set of use cases, related to the DMG project (<i>Dossier Médical Général</i>). The following description can therefore be seen as a working hypothesis, a suggestion that still needs further discussion and refinement.</p> <p>The Patient Summary is a condensed overview of the patient's current state of health, as far as it is known in the eSanté platform. It is a special type of clinical document that is initialized, validated and maintained by the patient's Reference Doctor, and located in his SPHR.</p> <p>The following list shows examples of the categories of health information that might be contained in the PS:</p> <ul style="list-style-type: none"> • Blood group and marker determination • Current medication • Medication incompatibilities • Allergies, adverse reactions • Antecedents / family history • Chronic diseases • Vaccinations • Risk factors • ... <p>The information contained in the PS comes from different sources, the most important being the Reference Doctor himself. He initiates and maintains the PS based on his own exams and findings, and with information gathered from other clinical documents from the SPHR, such as specific lab results, e.g. blood group determination, cholesterol levels etc.</p> <p>To facilitate this task of the Reference Doctor eSanté offers him the possibility to search in existing documents of the SPHR. He can then choose individual elements from the results of this research in order to incorporate them into</p>

²⁹ Actually it's even more complicated, because the TTP never returns the pseudonym directly to an external user of the platform. Instead it returns a time-limited transaction ID which the eSanté platform can then use during a well defined time window to obtain the real pseudonym from the TTP, and with it get to the patient's SPHR.

Term	Description
	<p>the PS. Standard codes such as ICD10 should be provided by eSanté if possible, in view of the generation of an international PS³⁰.</p> <p>At the end the Reference Doctor submits the PS to the SPHR as a new document, or as an updated version.</p>
PMS	<p>The PMS or Patient Management System is a Health Care Professional Software that supports a HCP in the management of his patients. Those systems have usually a database containing both administrative/demographic and medical information about patients. Other functions such as billing, letter generation, agenda and waiting room management often complete the PMS to a Medical Cabinet Management System.</p>
Prescriber	<p>(also sometimes called <i>prescribing physician</i>) is, in the context of LABO, a doctor who has prescribed a laboratory test to his patient. It is, however, not a formal role in the LABO use cases. What is important about the prescriber is that he receives the results of his test prescriptions, and therefore the use cases rather calls him the data consumer/recipient. There is also the similar concept of the reference doctor, which is in most of the cases also the prescriber of an test. But this doctor has other functions that go beyond making prescriptions.</p>
PS, Patient Summary	<p>The Patient Summary concept hasn't been integrated into the eSanté platform, yet. Its detailed description should become the subject of a different set of use cases, related to the DMG project (<i>Dossier Médical Général</i>). The following description can therefore be seen as a working hypothesis, a suggestion that still needs further discussion and refinement.</p> <p>The Patient Summary is a condensed overview of the patient's current state of health, as far as it is known in the eSanté platform. It is a special type of clinical document that is initialized, validated and maintained by the patient's Reference Doctor, and located in his SPHR.</p> <p>The following list shows examples of the categories of health information that might be contained in the PS:</p> <ul style="list-style-type: none"> • Blood group and marker determination • Current medication • Medication incompatibilities • Allergies, adverse reactions • Antecedents / family history • Chronic diseases • Vaccinations • Risk factors • ... <p>The information contained in the PS comes from different sources, the most important being the Reference Doctor himself. He initiates and maintains the PS based on his own exams and findings, and with information gathered from other clinical documents from the SPHR, such as specific lab results, e.g. blood group determination, cholesterol levels etc.</p> <p>To facilitate this task of the Reference Doctor eSanté offers him the possibility to search in existing documents of the SPHR. He can then choose individual elements from the results of this research in order to incorporate them into</p>

³⁰ Promoted by the epsos project, <http://www.epsos.eu>

Term	Description
	<p>the PS. Standard codes such as ICD10 should be provided by eSanté if possible, in view of the generation of an international PS³¹.</p> <p>At the end the Reference Doctor submits the PS to the SPHR as a new document, or as an updated version.</p>
Reference Doctor	<p>A physician who has a special trust relationship with a patient. In the eSanté platform the reference doctor has special privileges and functions in respect with his patients' medical data such as:</p> <ul style="list-style-type: none"> • having a privileged access to his patient's medical data record • to unblock critical data so that the patient can see them³² • sharing his patient's medical data with other HCPs in agreement with the patient <p>He also happens to be the principal prescriber of most of the patient's tests.</p>
SPHR	<p>A SPHR or Shared Patient Health Record is an electronic health record for individuals that is located on the eSanté platform, and which can be viewed by anyone who has the necessary electronic credentials to access this information.</p> <p>An ideal SPHR would provide a complete and accurate summary of the health and medical history of a person by gathering data from many sources.</p>
SPHR	<p>A SPHR or Shared Patient Health Record is an electronic health record for individuals that is located on the eSanté platform, and which can be viewed by anyone who has the necessary electronic credentials to access this information.</p> <p>An ideal SPHR would provide a complete and accurate summary of the health and medical history of a person by gathering data from many sources.</p>
Test Validation	<p>Today it is common practice and also a quality requirement that laboratories validate test results in a three-step process:</p> <ol style="list-style-type: none"> 1. automatic validation by the test equipment and its controlling software 2. technical validation by a lab technician 3. clinical validation by the responsible lab biologist <p>The publishing of results largely depends on these states of validation, but can be different depending on the lab. A lab hospital e.g. may publish technically validated results to services within the hospital, but only clinically validated results outside the hospital. Private labs in general would only publish clinically validated results. Tests that are only automatically validated should never be made available outside the laboratory.</p>
Trusted Node	<p>The lab's LIS communicates with eSanté through a special connector software that authenticates the LIS by means of a certificate. This secure authentication method, among other requirements, makes the LIS a so called Trusted Node for the eSanté platform.</p> <p>One consequence is that the validating lab biologists do not have to login directly into eSanté, and therefore do not need to be authenticated personally with eSanté.³³</p>

³¹ Promoted by the epsos project, <http://www.epsos.eu>

³² This function is not limited to the reference doctor.

³³ This is what IHE-ATNA profile suggests: secure notes can trust each other with local logins.

Term	Description
TTP	<p>Short for Trusted Third Party - is a component of the eSanté platform that allows for the pseudonymisation of a patient's identity, for the purpose of providing a secure reference to a patient without revealing his actual identity in combination with his medical data. This is achieved by sending demographic patient identification information to the Master Patient Index, which in case of a positive match returns a unique ID which is then exchanged for a pseudonym by the TTP. This pseudonym replaces the patient information in the data sets stored on the eSanté platform, so that medical data is not stored together with readable patient identification information.³⁴</p>
Unblock Code	<p>A code composed of numbers and letters that is generated by the Lab and printed on the paper report that is sent to the doctor (and NOT on the one sent to the patient!). It is also present in the electronic report sent to eSanté, where it is both in the meta-data and the document content.</p> <p>This code can be used by the patient, and only by the patient, to unblock reports that the labo has blocked for patient reading. As long as the report is blocked the patient cannot see the code³⁵, and only HCPs can see this code, either on the printed report or the electronic one in eSanté.</p> <p>During the «<i>visite d'annonce</i>» the doctor may give the unblock code to the patient, as an alternative to do the unblocking himself. Now a patient can use this code to unblock the document himself and thus gain permanent access to the report.</p> <p>This mechanism is meant to facilitate unblocking of blocked documents for the doctor, because he has not to perform himself the special unblocking operation, which requires to be connected to the platform and have access to the patient's SPHR (see LAB-UC3 - Single Patient Data Viewing & Import, extension 7.a.1.)</p>
Unique Document ID	<p>The eSanté platform identifies all documents that are held in its document registry with a so called Unique Document ID (UDID). This UDID is returned after a successful submission of data to the platform in LAB-UC1 - Labo Data Provider use case, and can be used later to refer to the document, e.g. to cross-link documents that belong to a series (e.g. partial results with complete report, radiology report and its addendums etc.), or to cancel / invalidate / make obsolete a complete document (see use case LAB-UC2 - Lab Result Cancellation & Replacement).</p>
Visualization Options	<p>A report (partial or complete) that can be accessed over the eSanté platform may have different visualization options, depending on which type of user looks at it - patients may have a different view than doctors.</p> <p>The doctor sees an annotated and commented version (e.g. highlighting abnormal values, additional commentary text, etc.) while the patient receives the "raw", uncommented version, in order to not alarm him. These annotations and comments are sometimes called an "interpretation", but do not constitute a different type of lab document.</p>

³⁴ This is only appropriate for data where the patient identification info can be removed automatically and without compromising the data's integrity. Good examples are: structured radiology reports, labo results in XML format. Bad examples are: text documents such as Word and PDF documents, bitmap pictures with embedded text, scanned reports and letters, etc.

³⁵ The unblock code will not be displayed in the meta-data that the patient can see.