



Research

# SELF-e study Nestlé - SunnyLake



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Nestlé Research Center

# Study objectives



## General objective

- ✓ Allow people to self-monitor, control and manage their health via digital tools

## Primary Objectives of the study

- ✓ To establish that e-health data from different devices and different providers can be captured on-line, integrated into a clinical database and made available for analysis alone or in combination with clinical data from other sources.

# Study description



## **Pilot study:**

- 70 participants for 3 months
- 50 participants for 1 year



## **Duration:**

from 3 months to 1 year



## **Location:**

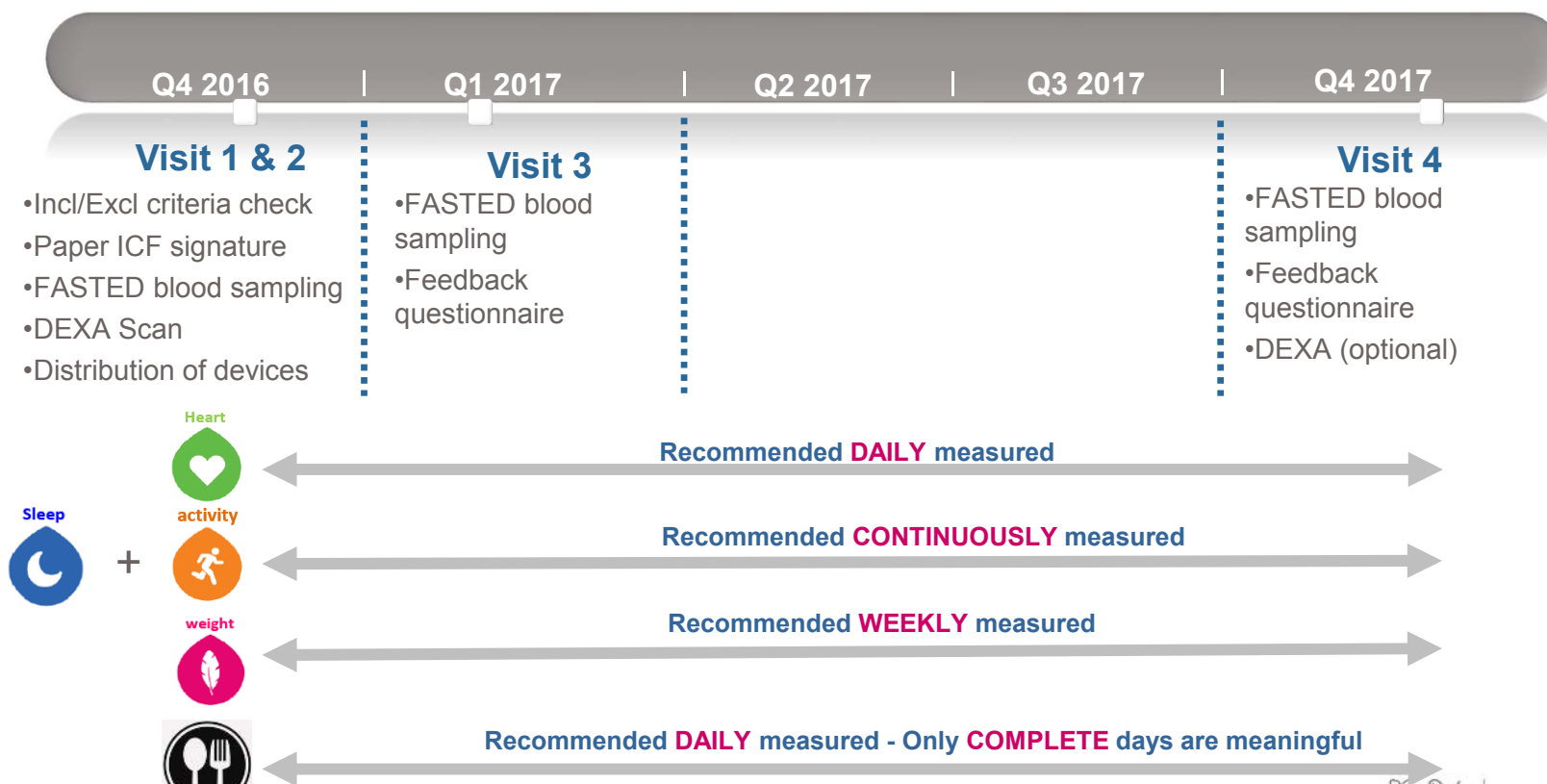
Conducted at the Nestlé Metabolic Unit



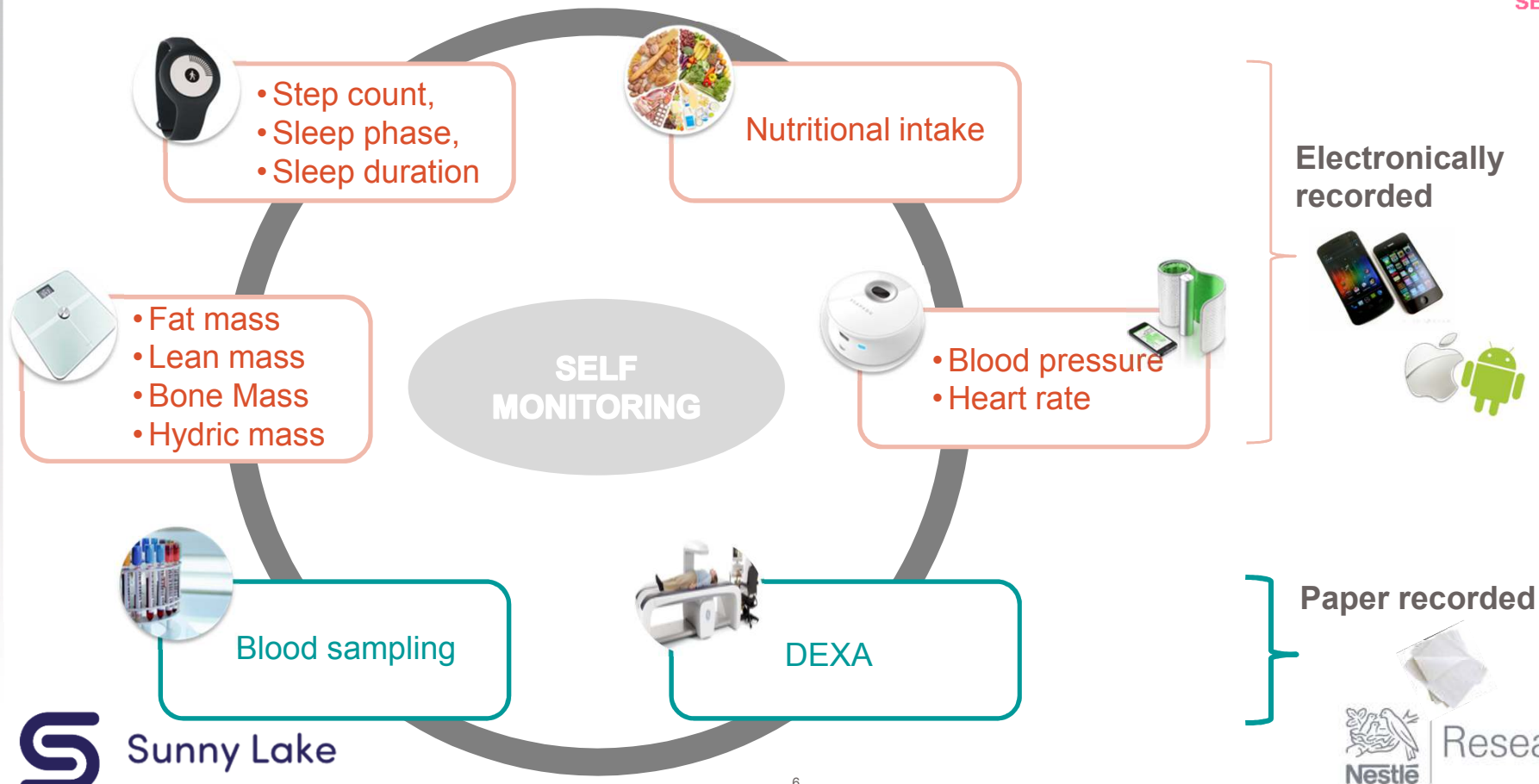
## **Collaborations:**

- Scanadu
- Withings
- Nestlé Globe
- Nestlé Institute of Health Sciences (NIHS)

# Visit Schedule



# Data collected



# Ethics Committee feedback



After 1<sup>st</sup> submission, EC came back with 35 questions, a lot regarding data protection and data confidentiality.

Examples:

- ① Veuillez détailler quelles sont les données et informations collectées par les dispositifs de mesure et applications smartphone et soumettre à la CER-VD les notices d'utilisation des dispositifs utilisés et, le cas échéant, les documents d'instructions distribués aux participants, ainsi que le questionnaire de retour d'expérience.
- ② Cette étude implique la collecte d'un très grand nombre de données personnelles via différents systèmes/dispositifs/applications. Veuillez clairement détailler les mesures prises par le promoteur pour assurer la protection des données des participants à l'étude.
- ③ Lignes 187-188 "*En utilisant les applications de tiers, vous acceptez leurs conditions générales d'utilisation et de partager vos données personnelles avec eux.*" : Cette dernière disposition n'est pas acceptable dans le cadre d'une étude. C'est au promoteur d'assurer que la confidentialité des données transférées via les applications est conforme à la réglementation suisse et que l'utilisation des données ne se fera que dans le cadre de l'étude. Si ce n'est pas le cas, il est impératif de fournir aux participants une information claire et précise des conditions d'utilisation et de la gestion des données qui sera faite par le(s) fournisseur(s) de l'application.

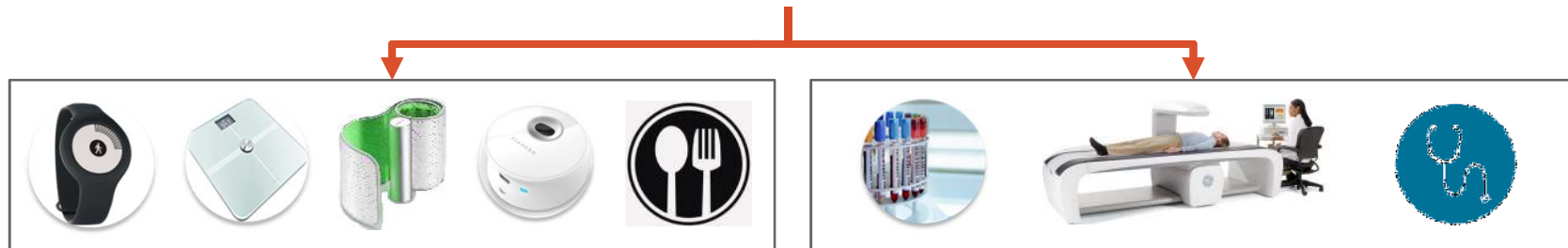


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# Data flow



70 Volunteers



Real Life Data

Observed Clinical Data

Through "fake" email address



Vendor Databases



Research



# Data confidentiality



How to keep subject confidentiality when using external App?

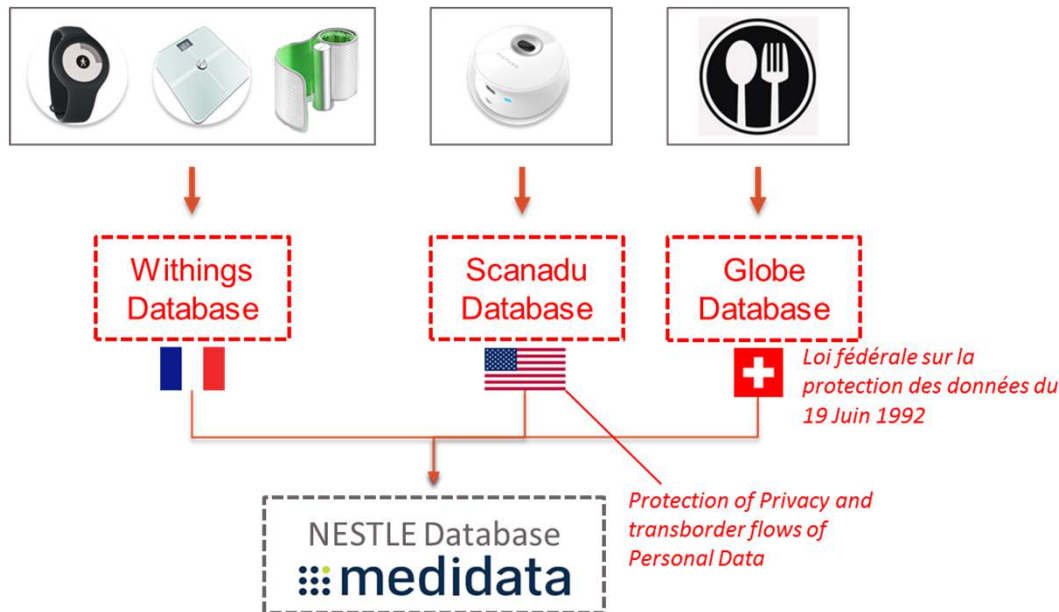
Onboarding procedure created for each subject with use of “fake” email address:

1. Enter your anonymous **e-mail address and password provided to you by the Metabolic Unit, it is extremely important to ONLY use this email:**

<b>Your study email:</b>	<b>1606nrc.che001+0002@gmail.com</b>
<b>Your study password:</b>	.....

2. Enter 1606nrc-che001 as first **name**.
3. Enter 0002 as **name**.
4. **Date of birth:** fill in your date of birth.
5. **Sex:** fill in your gender
6. **Height:** fill in your height.

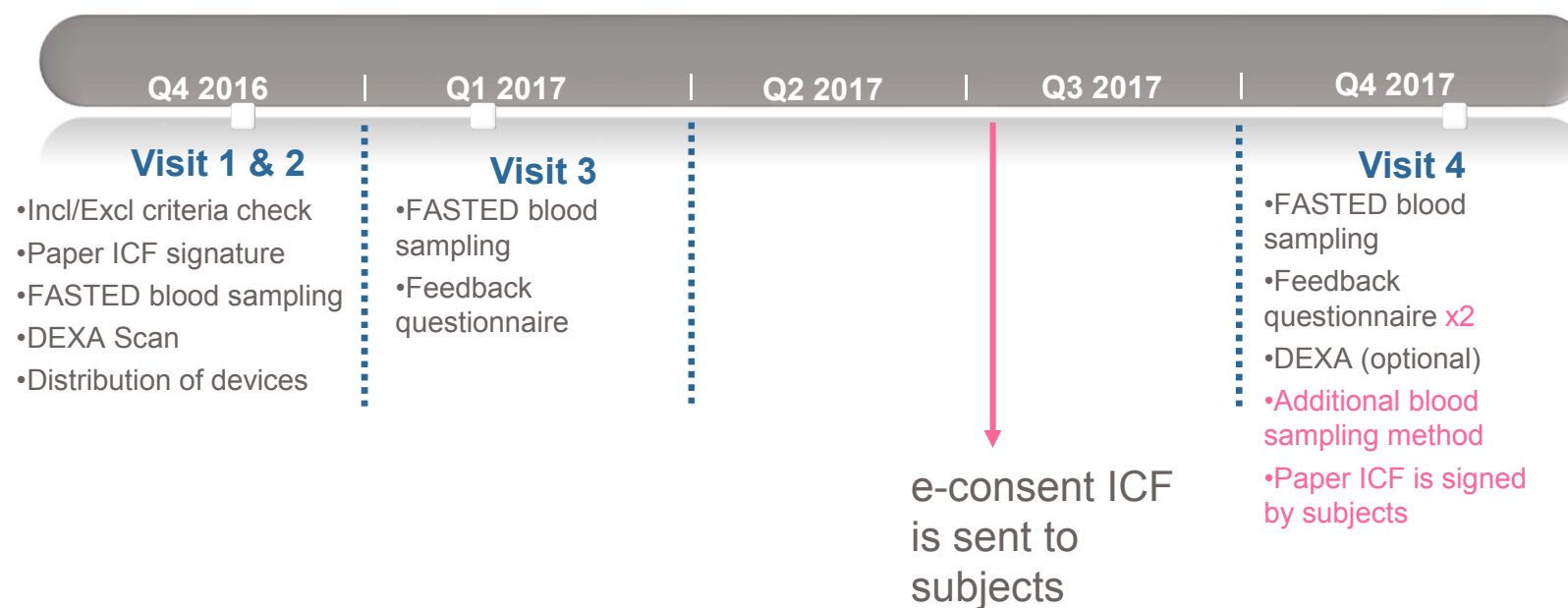
# Data protection



**Ethical Committee request:** “This study involves the collection of a lot of personal data via different systems / devices / applications. Please clearly detail the steps taken by the sponsor to ensure the data protection of study participants.”

- ✓ Data Privacy: Coding of personally identifiable information (anonymization)
- ✓ Data Security: Both physical & operational

# Visit Schedule



# E-consent- objectives



Remote signature-  
Speed up the process  
for the site and subject



Blockchain- Ensure  
the security of the  
data for the subject



No information visit-  
Ensure that the subjects  
get enough information  
on the platform



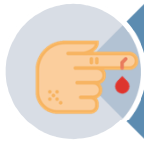
Unique set of  
keys- Enable the  
subject to be the  
owner of his data



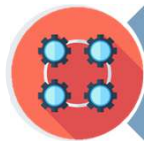
# E-consent set-up



Protocol amendment



Additional blood sampling method



Set-up on a Nestlé internal virtual machine



UAT outside of study team

# Ethics committee review



## Feedback from the Ethics Committee

- E-consent is not yet permitted as a paper ICF alternative
- Must have both paper and e-consent signed in parallel



POC results and feedback provided at the end of the study

# E-consent timeline



Participants receive:

- link to the e-consent platform
- support material
- link to plan visit 4



Information session: the e-consent is explained to the subjects



The subjects sign the e-consent or not, the PI counter-signs → one month



The subject comes to the MU, signs paper ICF if amendment is accepted and visit 4 is carried out accordingly



# Easy to manage e-consent for P.I.

Just 3 steps to reach participants

1. Add ICF and information note

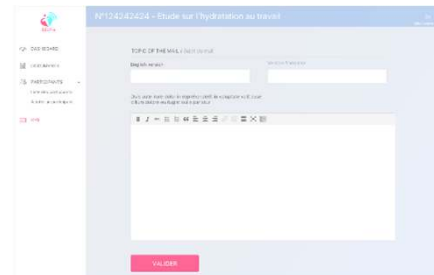
2. Create e-mail for recruitment

3. Add participants e-mail

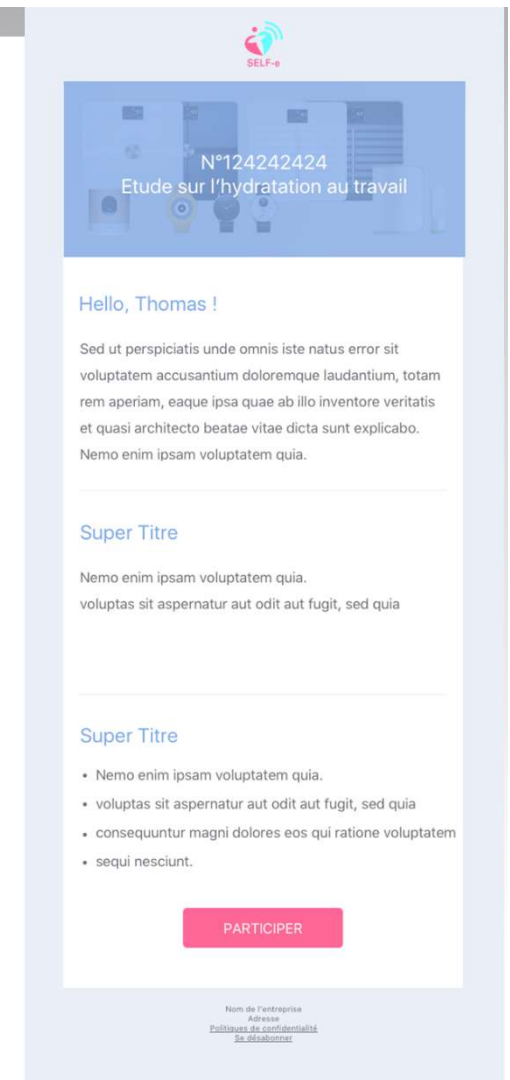
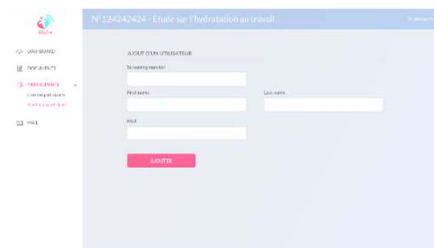
1



2

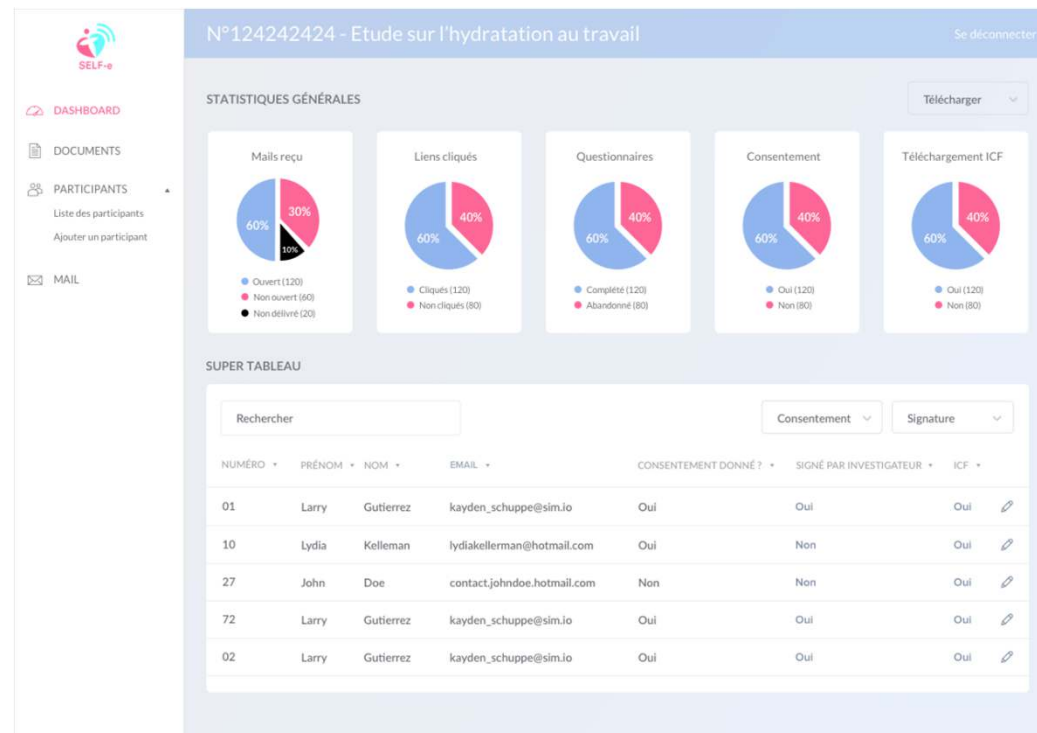


3





# Easy to monitor e-consent for P.I.



# Consent collection



## Comment ça fonctionne ?

Sed ut perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem



étape 1  
Prenez connaissance  
de l'étude et son protocole



étape  
Lorem ipsum dolor sit  
amet, consectetur  
adipiscing elit



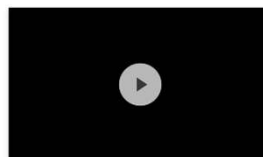
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adipiscing elit

**Clear e-consent information**



**Clear study information**

## La vidéo de l'étude



**Video about key elements of protocol**

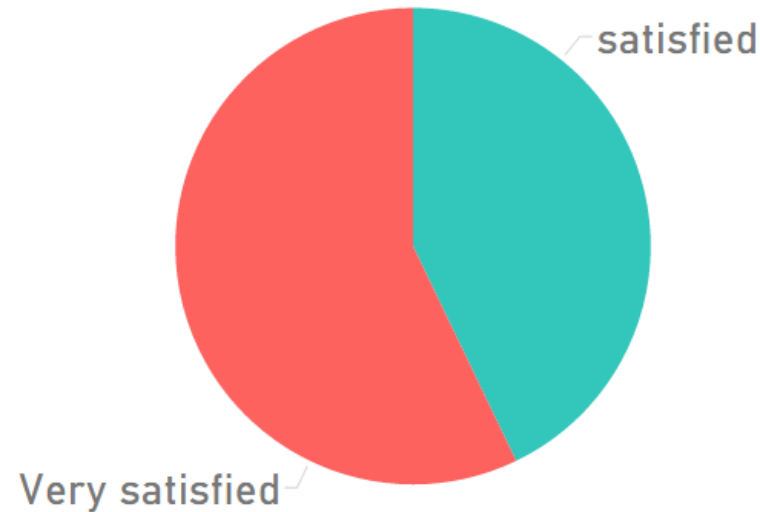
# A new design thinking of informed consent



Participants receive key information through  
a **quick and clear** motion design video



# How satisfied were you with the video describing the amendment?



# User experience is key

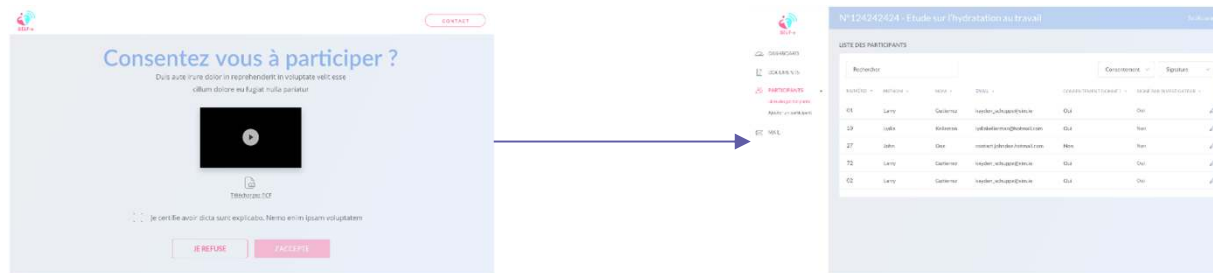


**Investigators** are assured that every consent is **really informed**.

- Questionnaire about key points of the study
- Invalid answers are explained to the participant



# Time-stamped consent on Bitcoin blockchain



- 1 Participant sign the ICF
- 2 P.I. countersign the ICF
- 3 ICF is sealed on the public blockchain, respecting all privacy concerns  
No personal information disclosed on the blockchain

# Checking consent on the public blockchain ...



```
1 {
2   "firstName": "0",
3   "lastName": "F",
4   "screenNumber": "3456709876543",
5   "downloadIcon": true,
6   "downloadInformationLetter": true,
7   "startAnswering": "2017-09-06T13:31:28.000Z",
8   "finishAnswering": "2017-09-07T15:26:52.000Z",
9   "icfIdx": "xelak-supyc-nureg-ryzyn-cetub-lakyk-cinal-vidav-kegyr-kahyg-vidib-sulov-dudiv-rysam-rygef-rysok-goxyx",
10  "letterIdx": "xebis-sofub-kavez-fetag-deton-zugic-kemym-syrag-kivev-canug-cetav-zufot-kacic-pymep-padog-lovup-hixyx",
11  "studyRefIdx": "xozal-vidik-ripih-capic-zozec-fevod-tehuc-burum-cabev-pekac-vurob-mecih-huroc-mysil-madiz-numym-cyxax",
12  "study": 14,
13  "date": "2017-09-07T15:30:51.458Z",
14  "agree": true,
15  "answer": {
16    "1": "correct",
17    "2": "correct",
18    "3": "correct",
19    "4": "correct",
20    "5": "wrong",
21    "6": "correct",
22    "7": "correct",
23    "8": "correct",
24    "9": "correct",
25    "10": "wrong"
26  }
27 }
28 /*
29 keex self xosem-kesin-cameb-dudof-bohuv-radad-zoril-zatad-nycos-danup-pyric-vobik-vazon-tifog-kucaz-zazuk-rexus, {main} keex
30 keex self 3E7fyjh5994ab4jfs7LJoc2Dr578FSA1zF9bDAK, {alg:sha224, enc:BS8, recursive:1} keex
31 keex name "3456709876543-agreement.json", {main} keex
32 keex prop "kx.author", "rumod-zusyl-kotug-carar-mefan-geruv-hihud-bumom-keteb-movil-lemef-syriv-cutur-lomym-tymyv-bocic-nexer" keex
33 keex prop "kx.description", "Participant 3456709876543 agreed study 14" keex
34 keex prop "kx.time", "Thu, 07 Sep 17 15:30:51 +0000" keex
35 keex ref "rozal-vidik-ripih-capic-zozec-fevod-tehuc-burum-cabev-pekac-vurob-mecih-huroc-mysil-madiz-numym-cyxax" keex
36 keex ref "relak-supyc-nureg-ryzyn-cetub-lakyk-cinal-vidav-kegyr-kahyg-vidib-sulov-dudiv-rysam-rygef-rysok-goxyr" keex
37 keex ref "rebis-sofub-kavez-fetag-deton-zugic-kemym-syrag-kivev-canug-cetav-zufot-kacic-pymep-padog-lovup-hixyr" keex
38 keex prop "kx.publickey", "1MnxvG5j4Kks8ZBggr4BAc55jXmRda8kTg", {bitcoin} keex
39 keex protected "Ich18qb95VsyP3VCbN6A80J39:KXDR01BL18d1X1K8BCRL1L6MGBfjNpU4AB:qvc:Gm49Ymh2kqWFA9Se1BskU=", {bitcoin} keex
40 */
```



# ... with a seamless and intuitive tool



## Certificats Blockchain récents

ID de transaction	Age	Horodatage
<a href="#">f2bab30ab3...</a>	23 hours ago	Wed, 21 Feb 2018 12:00:04 GMT
<a href="#">b3c6ff01d0...</a>	1 day ago	Tue, 20 Feb 2018 12:00:02 GMT
<a href="#">b742a611d8...</a>	2 days ago	Tue, 20 Feb 2018 00:00:04 GMT
<a href="#">fe2a5fccd2...</a>	2 days ago	Mon, 19 Feb 2018 12:00:04 GMT
<a href="#">f124f01109...</a>	4 days ago	Sun, 18 Feb 2018 00:00:02 GMT

[Voir tout les certificats](#)

## Horodatages récents

IDX de fichier	Age	Horodatage
<a href="#">xoheb-figov-popyr...</a>	29 minutes ago	Thu, 22 Feb 2018 10:45:21 GMT
<a href="#">xuzob-pabat-fizyl...</a>	44 minutes ago	Thu, 22 Feb 2018 10:30:31 GMT
<a href="#">xepot-fetyl-sasen...</a>	44 minutes ago	Thu, 22 Feb 2018 10:30:09 GMT
<a href="#">xofog-zamar-sukoz...</a>	44 minutes ago	Thu, 22 Feb 2018 10:29:56 GMT



Le fichier est authentique et la signature de son auteur est valide. Vous pouvez avoir confiance en son contenu.



Empreinte de fichier (IDX) [xosem-kesin-cameb-dudof-bohuv-radad-zoril-zatad-nycos-danup-pyric-vobik-vazon-tifog-kucaz-zazuk-rexux](#)

Identité de l'auteur [1MnxvGSj4Kks8ZBGgr4BAc5SjXmRda8kTg](#)  
[Chercher sur Google](#) [Chercher sur DuckDuckGo](#)

Signature [lChl8qb95VSypV3VCbN6A8OJJ9+kXDROiBLi8d/X1K8BCRIll6MGbFINpU4AB+qvc+Gm49YmhkzqwFA9Se1BskU=](#)

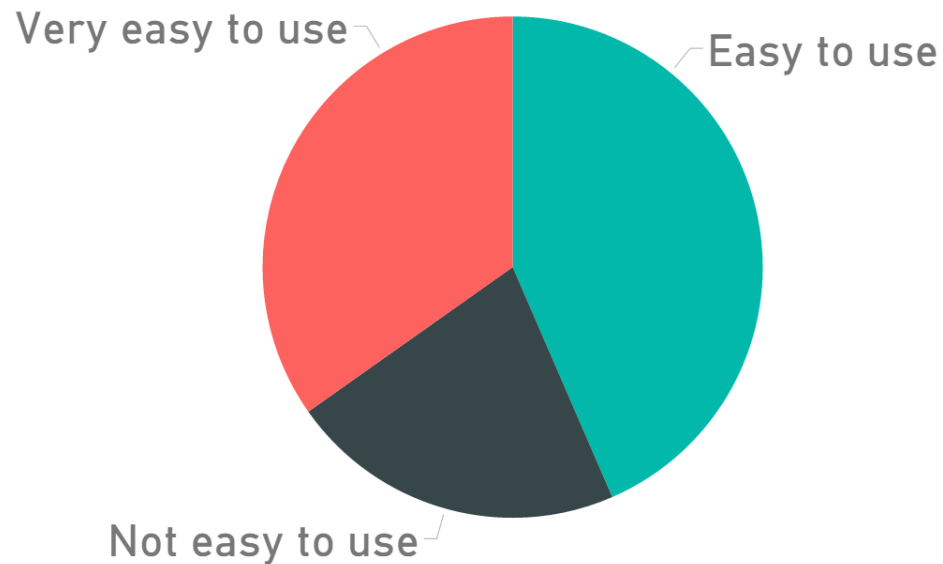
Certificat d'horodatage [Affichage du certificat d'horodatage](#)



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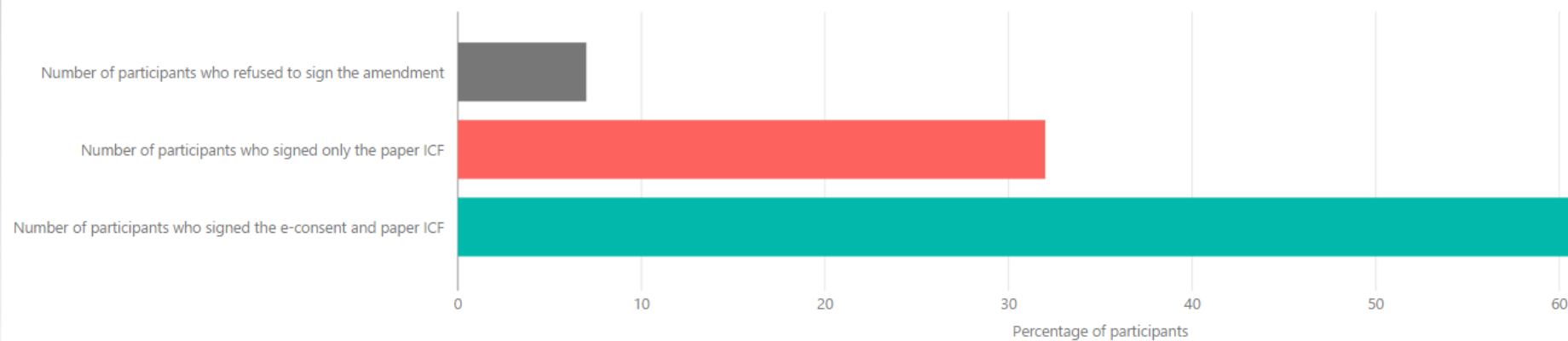
# Feedback on ease of use and understandability



Did you get enough information about amendment through the eConsent platform?

**Yes → 100%**

# Participation at V4



# Ideas for future developments



- ✓ POC demonstrates the feasibility of the solution and can be used as a base for a future development
- ✓ Make the platform more user friendly- simplify the blockchain consent process
- ✓ Regulatory framework on adaptability of e-consent
- ✓ Gather more cultural information on the category of population it would appeal to most

# Conclusion



**Trustworthy** e-consent bring **peace of mind** to both **participants and investigators**

**Paperless** consent collection allows easier way to **contact, inform and enroll** participants

**Easy to use, time-saving** interface

# Next steps



Improve the user authentication



**Frictionless** login  
Without **private/public key**  
induced difficulties

Survey module creation



Questionnaire with **time-stamped**  
**answers** allowing **safe**  
**collecting of patient reported**  
**outcomes**