

HEAD Registry

A pan-European registry to monitor the impact of allergic diseases and asthma

Users' guide

Outline

- Summary of protocol
- Before entering data
 - When to start
 - Patient selection
- Data sources and dates
- Entering data in REDCap
- Monitoring
- Updates
- Questions

Summary of protocol

Principal investigators

Prof. Dr. Ioana Agache (RO)

Prof. Dr. Maria Jose Torres (SP)

Protocol > Justification

- Allergic diseases and asthma stand as one of the most common chronic diseases globally, incurring a substantial global health burden.
- However, their actual impact is difficult to estimate due to the lack of representativeness and incompleteness of relevant data.
- In Europe, allergy care services are available in most countries, but there is significant heterogeneity between centres and between countries.
- Many allergic diseases are self-treated, treated by pharmacists or at the primary care level, without proper training in allergy, thus leading to a profound impact on quality of care and desired outcomes.

If we want to reduce unwanted variability and inequities, we must first provide data.

Protocol > Hypotheses

1. Management patterns –i.e., diagnostic tests, treatment, avoidance, and prevention—vary across and within countries.
2. The impact of allergic diseases and asthma on
 - the individual
 - society
 - healthcare system in Europeis significant,
 - overall (as allergic diseases usually cluster together)
 - for each specific disease (allergic rhinitis, asthma, atopic dermatitis, chronic urticaria, drug allergy, food allergy)
3. The impact varies significantly by
 - disease severity
 - country
 - setting (primary care versus specialised care)
4. The impact of combinations of allergic diseases is higher than the sum of individual impacts.

Protocol > Objectives > Overarching aims

1. Collect data on allergic disease and asthma management across centres and countries.
2. Harmonise allergic diseases management by using this registry's results as the base for consensus recommendations and guidelines.
3. Establish a structure for collaborative projects in allergic diseases and asthma across countries.

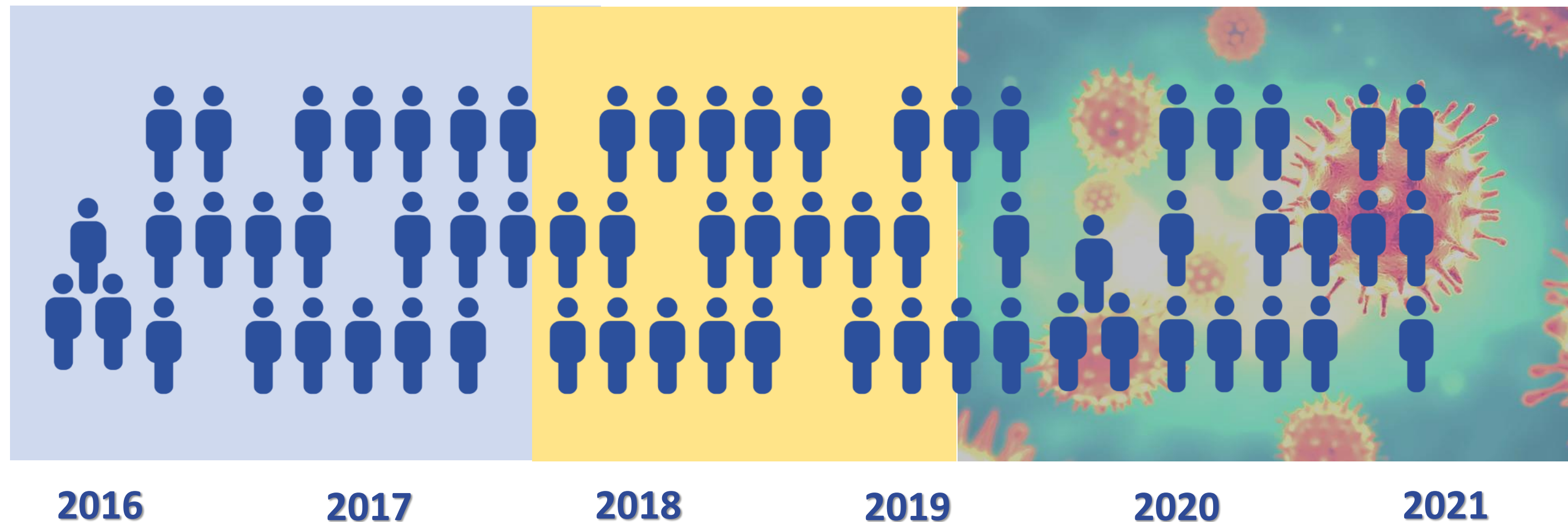
Protocol > Objectives > Study objectives

1. Describe **patterns of care** for allergic diseases and asthma across Europe

 2. Estimate the **impact**—in terms of
 - use of resources (healthcare perspective)
 - costs (societal perspective)
 - disability and personal costs (individual perspective)
-
- By allergic disease and their combinations
 - Stratified by disease severity
 - Stratified by age groups (paediatric versus adult population)
 - By country
 - By setting (specialised care versus primary care)

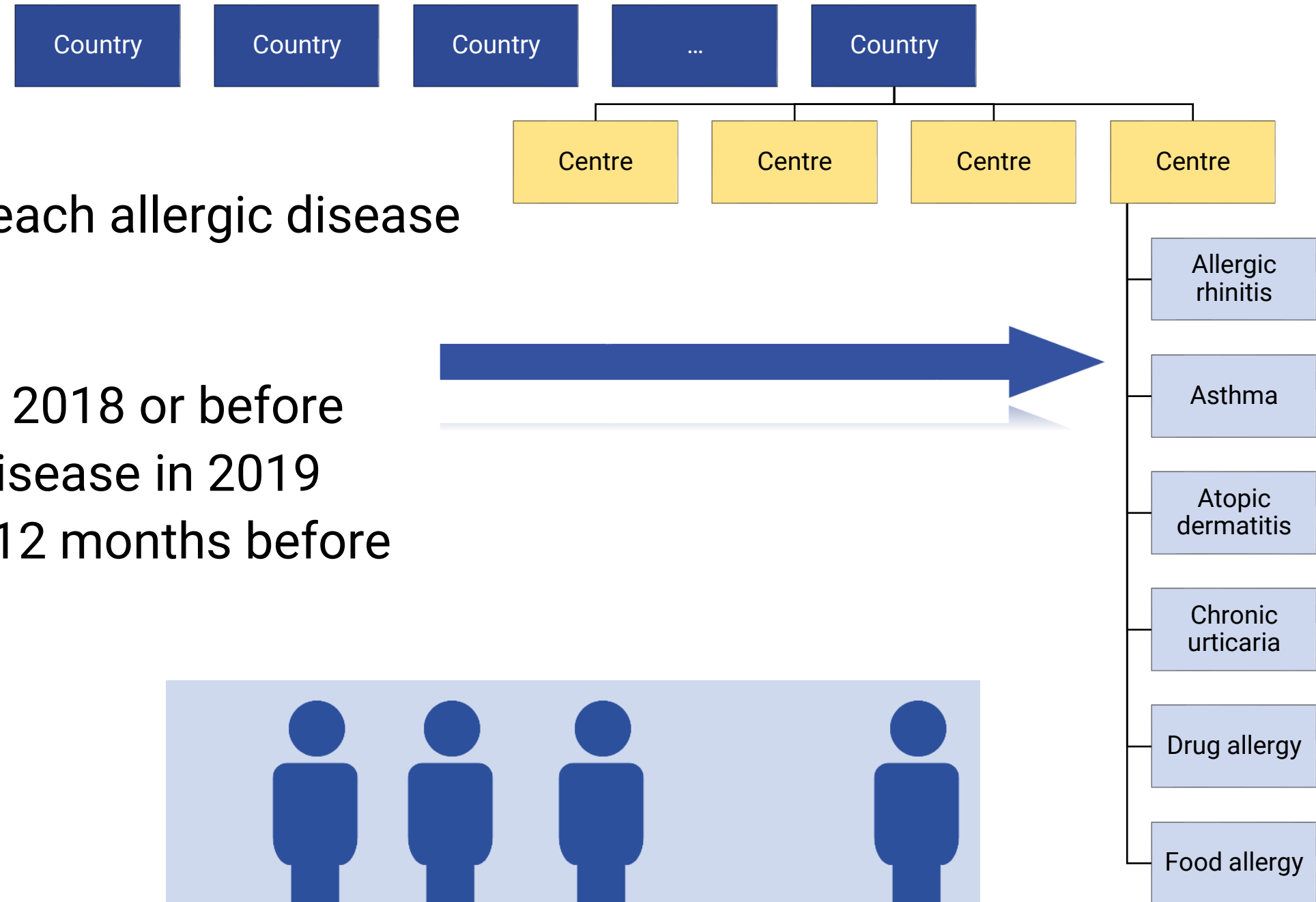
Protocol > Study design

- Cross-sectional study nested in a multinational registry
- Observation period 12 months



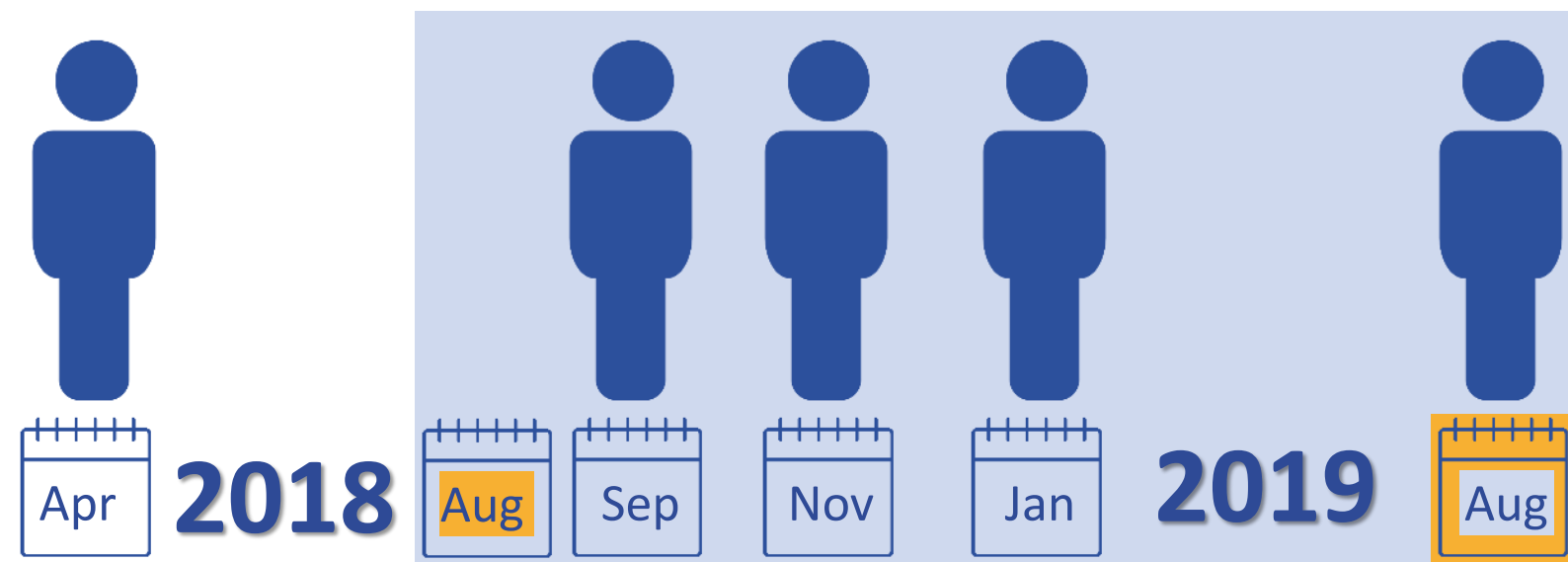
2018 - 2019 was chosen to avoid unrepresentativeness of patients attending the allergy clinic during the pandemics

Protocol > Study population



■ Inclusion criteria

- Specific diagnostic criteria for each allergic disease included
- Any age / Any gender
- Diagnosis of allergic disease in 2018 or before
- At least 1 visit for the allergic disease in 2019
- Access to information at least 12 months before the patient visit in 2019



Protocol > Study population > Patient selection I

Each NAS provides

- A list of centres willing to participate in the registry
- Info on public/private ratio in the country

This info is used to ensure a representative mixture of patients that mirrors the country population of patients with each allergic disease

Each centre

- Provides the n of eligible pts for each allergic disease included
- Produces a numbered list of patients for each allergic disease using an anonymous standard code

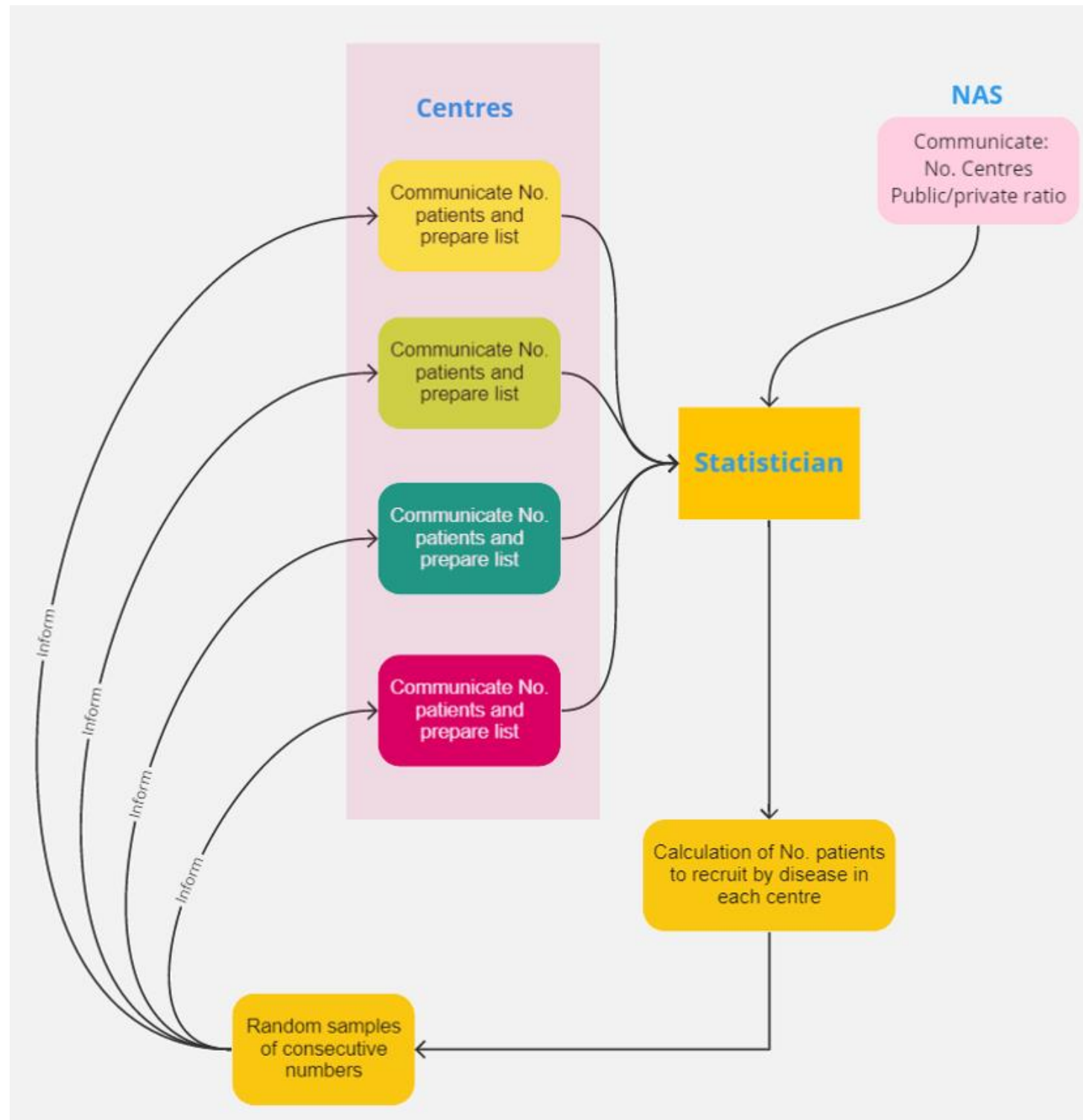
The technical team



- Calculates the number of patients needed to be included by centre and allergic disease
- Provides a list of random numbers by disease (including replacements)

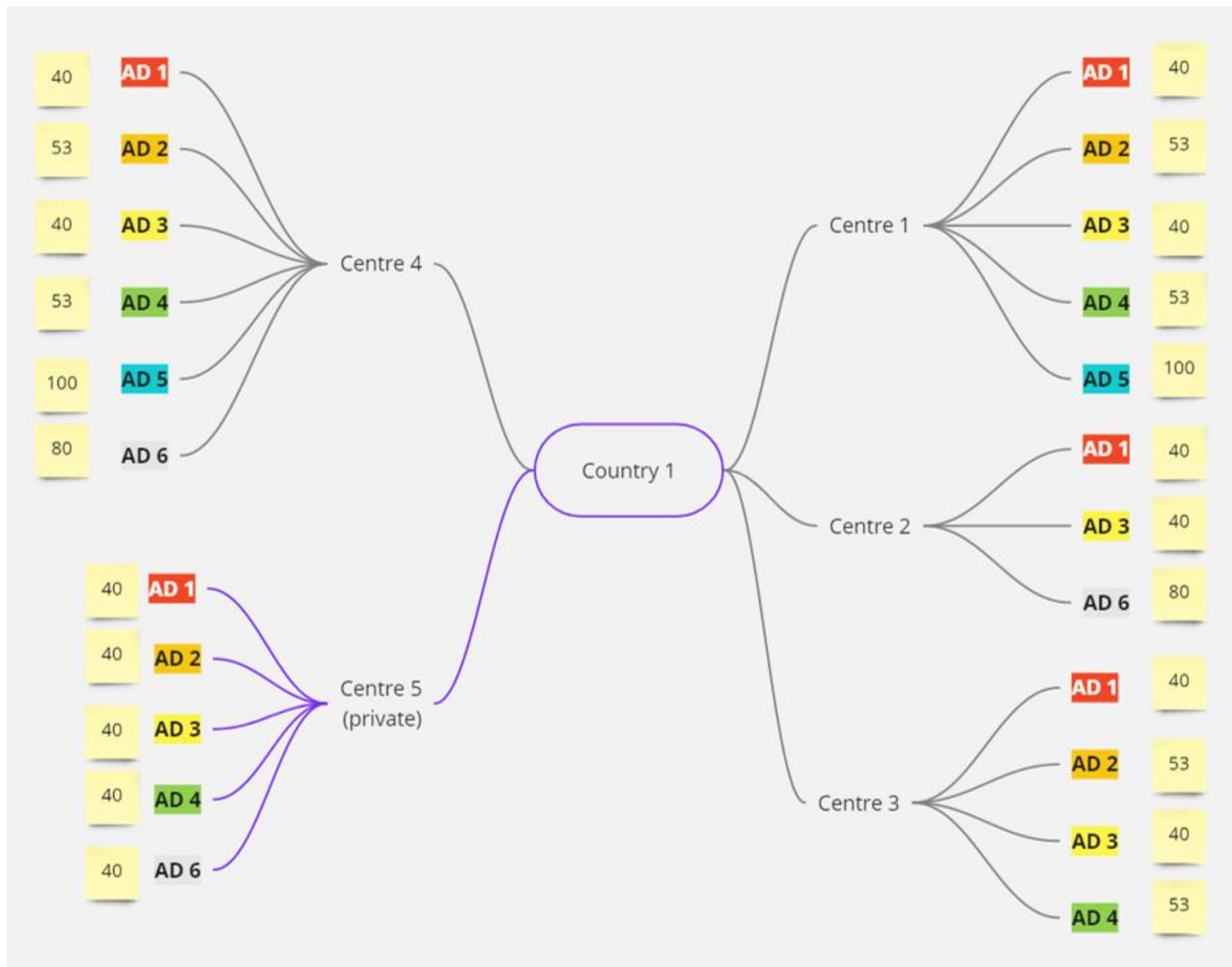
The technical team will ensure that 200 pts are allocated by disease in each country and that these patients are representative of the population of patients with that particular disease in that particular country

Protocol > Study population > Patient selection II



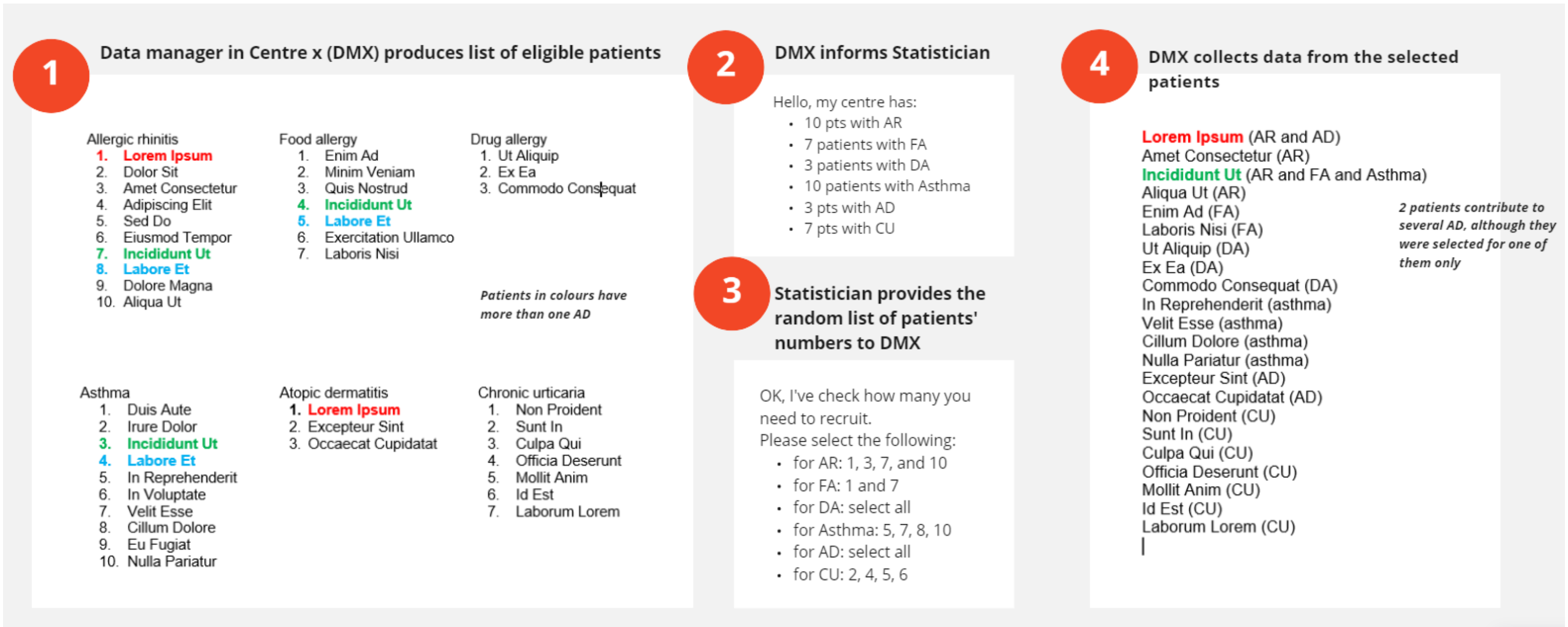
- The total number by disease / country is 200
- The statistician will calculate the number needed to recruit per centre based on:
 - the information provided by the NAS on the number and type of participating centres
 - the public/private ratio at the country level
 - the number of patients fulfilling the inclusion criteria in all participating centres in the country

Protocol > Study population > Patient selection III



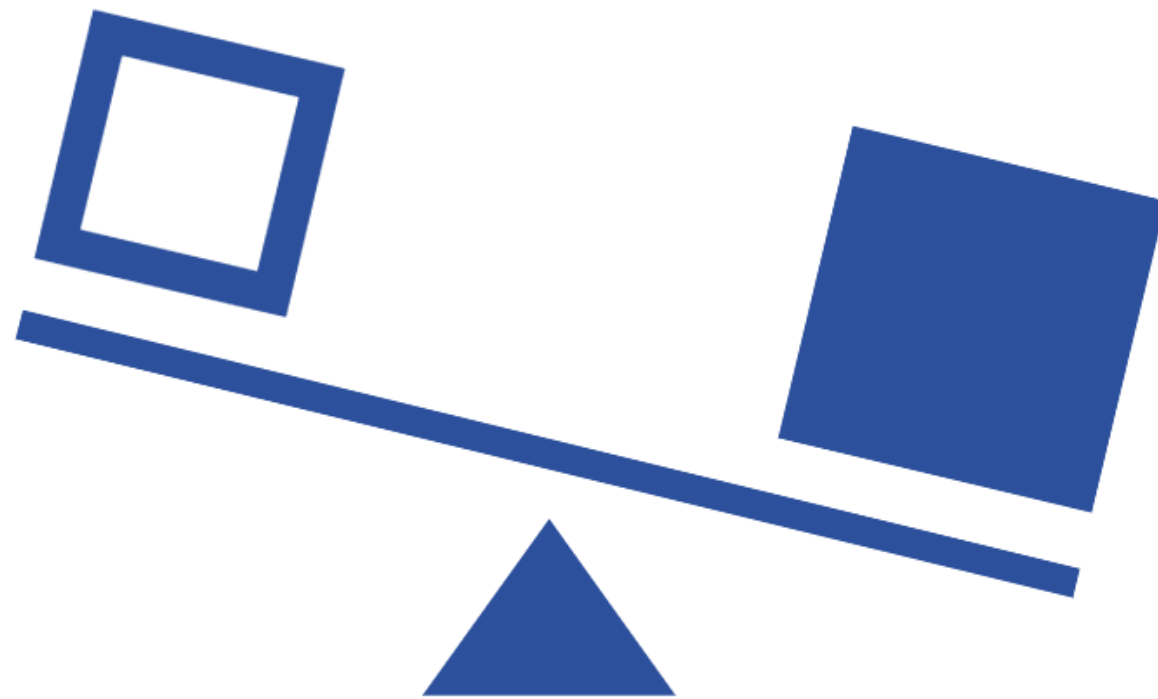
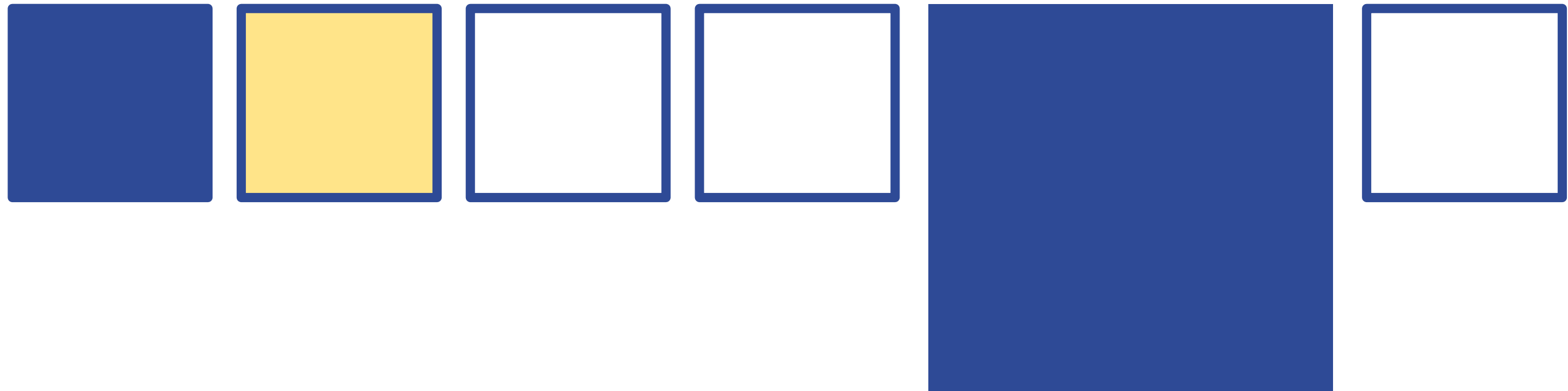
- In the example, out of the 5 participating centres, one is private (Centre 5).
- If the ratio public to private in the country is 5 to 1 (or 80% / 20%), that means that, to maintain the ratio, and for each disease (allergic disease = AD 1 to 6) this centre should select $200 \times 20\% = 40$.
- All other centres are public, say 3 hospitals and 1 primary care centre (centre 4).
- There are patients with disease AD1 available in all centres; therefore each public centre is asked to recruit $(200 \times 80\%) / 4 = 40$.
- For disease AD5, less centres have available patients meeting criteria (note that neither centre 2, nor 3 nor 5 have patients with that disease), thus a larger sample is needed in the 2 centres where AD5 is available; concretely, two centres must recruit $200 / 2 = 100$ patients.

Protocol > Study population > Patient selection IV



If a patient has several allergic diseases he/she will contribute separately to each disease evaluated; finally, the number of disease cases will exceed the number of patients (e.g., the patient is counted once for asthma, once for rhinitis and once for atopic dermatitis)

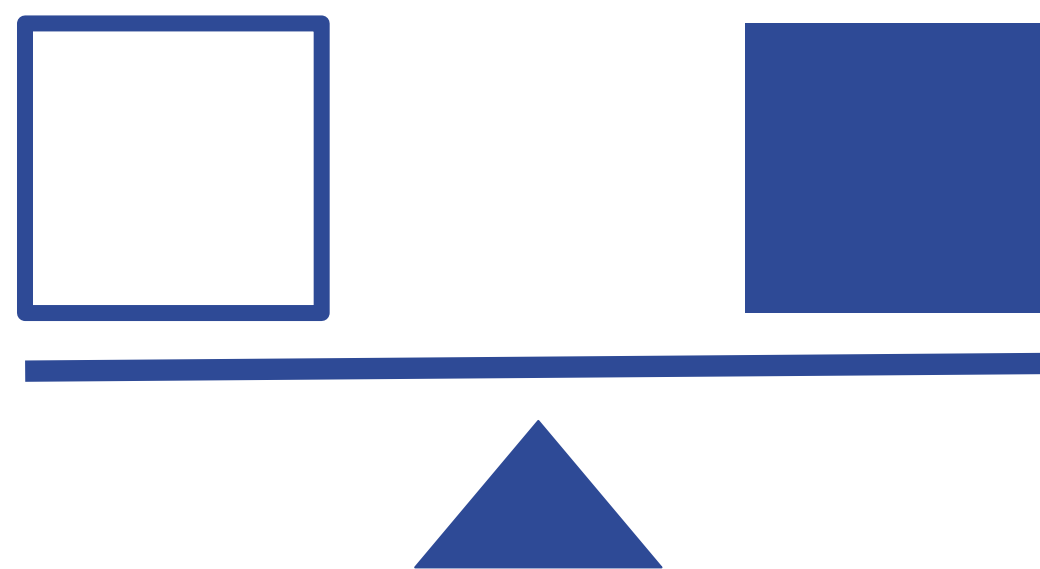
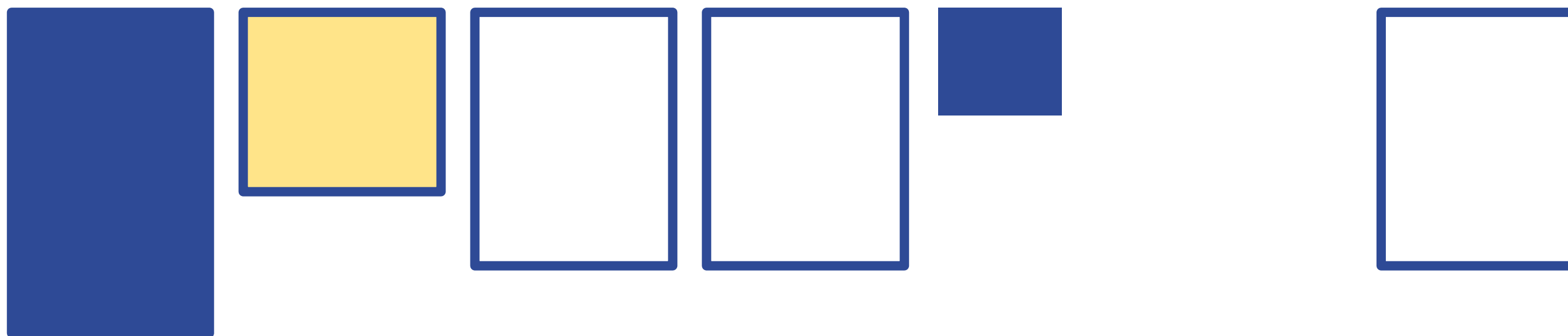
Why not ALL patients in a centre?



The sample per country must reflect the public/private ratio in the country and provide enough mixture of management patterns.

If too many patients from a single centre are included, the results lose generalisability

What if a centre / country does **NOT** have **ENOUGH** patients available?



The technical team will do the calculation to balance the sample at the country level by increasing the numbers proportionally in the other participating centres within the same country.

If there are not enough patients in one disease in one country we will not be able to make country estimations, but they will contribute to the European estimates.

Protocol > Outcome variables

Related to **management** patterns

- Diagnosis
- Interventions

Assessments and interventions will differ by disease

Related to **impact**

- Healthcare
 - Admissions (ICU/general Ward/day hospitalisation)
 - Visits for diagnosis/FU/Tx
 - Assessments
 - Interventions
- Society
 - Missed school days
 - Missed workdays
 - Disability pension/support
- Individual
 - Days lost not reimbursed
 - Costs paid by the patient

From patient charts + cross-checked with the patient

For this Info, the patient will need to be contacted

Descriptive

- Sociodemographic
- Risk factors
- Disease-related (controlled disease, criteria...)

Stratification variables

- Country
- Disease
- Severity
- Paediatric / adult
- Primary / specialised care

Protocol > Outcome variables > Data collection



List of selected patients



Contact the patient for consent

Open the CRF

If OK

Ask for impact data (out-of-pocket costs, other, and cross-check)

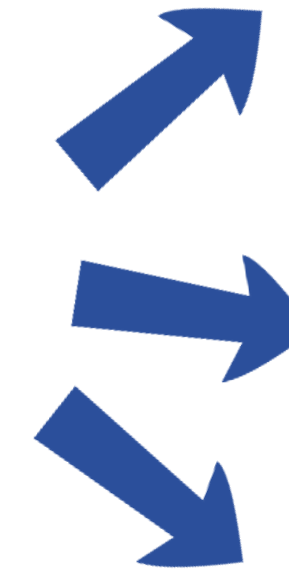
1st Check type of allergic disease

- Allergic rhinitis
- Asthma
- Atopic dermatitis
- Chronic urticaria
- Drug allergy
- Food allergy

e-CRF



Common costs



Allergic rhinitis



Asthma



Food allergy

Fill all corresponding e-CRFs based on the information included in medical records + patient data

Protocol > Informed consent I

- An informed consent template has been prepared for the registry, adapted to both adult and paediatric populations, describing the purpose of data collection in the registry, how the data will be handled, and who is going to access the data.
- The consent form will need to be adapted to the country's requirements and translated into the local language.

EAACI headquarters have some translations available.
National societies should check the translations or translate in case they are not available

- The subject will also be informed that only coded data will be transmitted to third parties and to other countries but in no case will they contain information that can directly identify him/her, such as name and surname, initials, address, DOB, etc.

Protocol > Informed consent II

- There is no consistent guidance at an international level for when and how to obtain consent.
- The participating investigators will be responsible for explaining to all selected patients, before their inclusion in the study, the nature, purpose, procedures and expected duration of the study, as well as the data that will be collected during their participation in the study.
- This will be done before collecting any data.
- Each patient will be given the necessary time to decide and ask the appropriate questions.

Protocol > Informed consent III

■ Options

- Inform by telephone and record in the clinical record that the patient was informed and consented; preferably this process should be witnessed by an external party

All by
telephone



- Send the consent form by e-mail and ask the patient to
 - Sign the pdf
 - Send a picture of the signed document for the clinical records

By e-mail



- Send the consent by post with instructions for the patient to
 - Sign and send it back to the clinic
 - Send a picture of the signed document for the clinical records by email

By post



- Ask the patient to attend the clinic for signing the ICF

In person

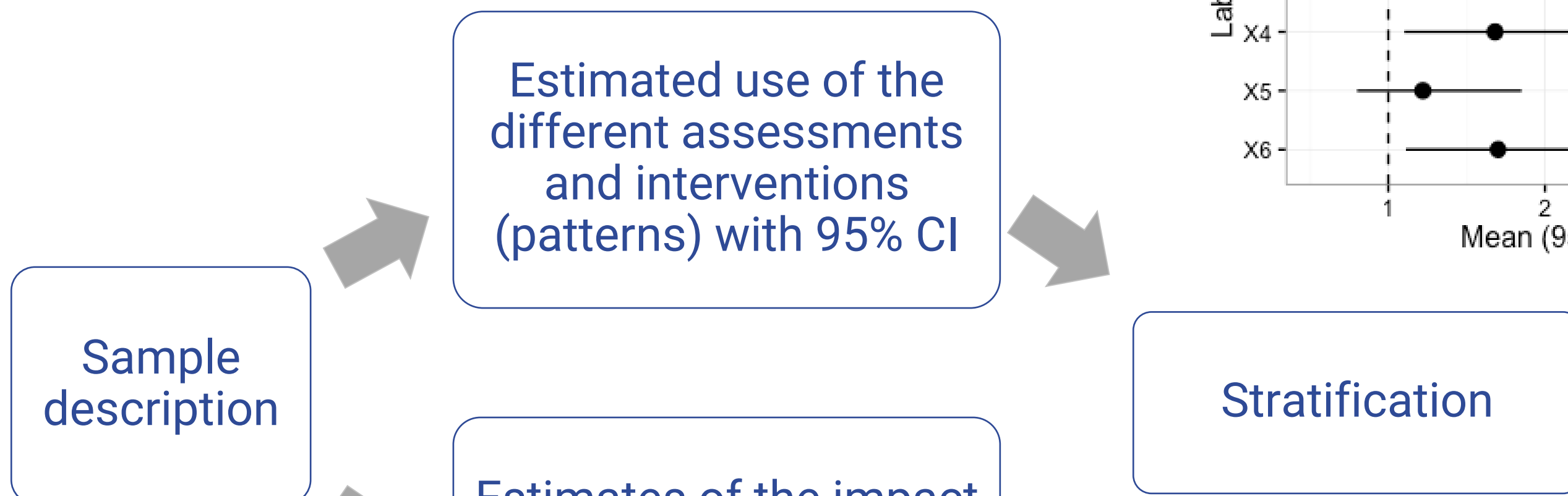


It is mandatory to document the ICF process in the clinical records

Protocol > Informed consent IV

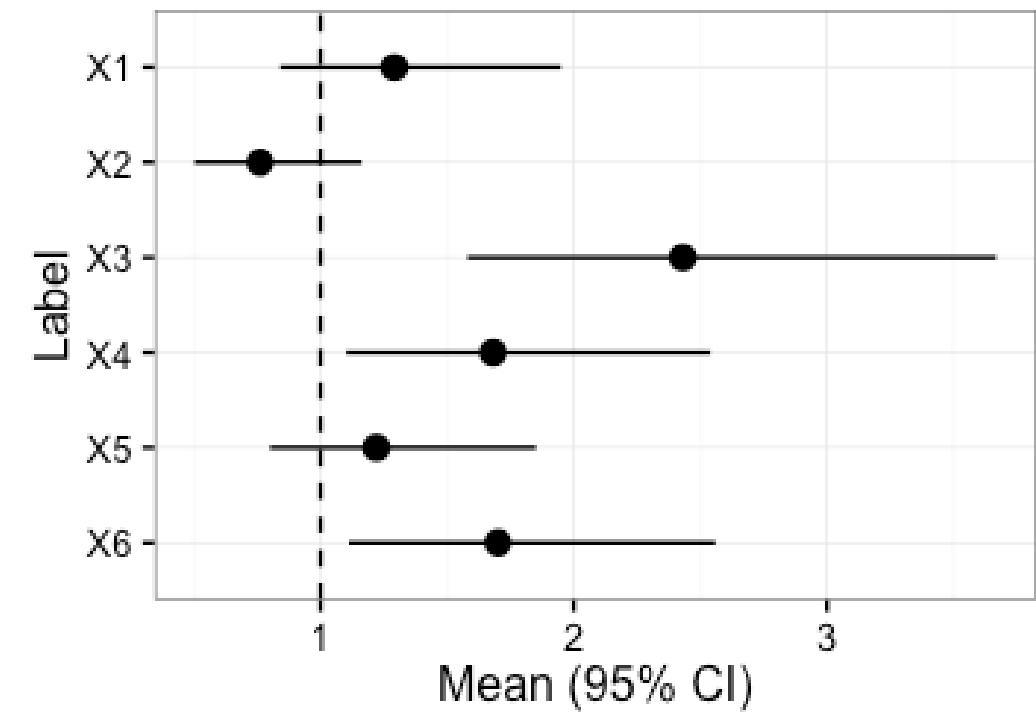
- Additional aspects
 - The informed consent process should be documented and made available for an audit or other inspections.
 - In no case should a signed consent leave the centre or be deposited in any other place.
 - Given the current health situation, in each country/centre, the Institutional Review Board should be asked about the possibility of the use of telemedicine procedures in order to obtain a verbal consent for data collection instead of a written consent (especially for the case of a retrospective, non-interventional data collection study)

Protocol > Statistical analysis



We might contact the national coordinators for information about specific costs

The intention is not to compare countries but to provide information by country and aggregated.
When aggregating data, weights will be applied.



Protocol > Data anonymisation and safety

1 Data manager in Centre x (DMX) produces list of eligible patients

Allergic rhinitis

1. Lorem Ipsum
2. Dolor Sit
3. Amet Consectetur
4. Adipiscing Elit
5. Sed Do
6. Eiusmod Tempor
7. Incididunt Ut
8. Labore Et
9. Dolore Magna
10. Aliqua Ut

Food allergy

1. Enim Ad
2. Minim Veniam
3. Quis Nostrud
4. Incididunt Ut
5. Labore Et
6. Exercitation Ullamco
7. Laboris Nisi

Drug allergy

1. Ut Aliquip
2. Ex Ea
3. Commodo Consequat

Patients in colours have more than one AD

Asthma

1. Duis Aute
2. Irure Dolor
3. Incididunt Ut
4. Labore Et
5. In Reprehenderit
6. In Voluptate
7. Velit Esse
8. Cillum Dolore
9. Eu Fugiat
10. Nulla Pariatur

Atopic dermatitis

1. Lorem Ipsum
2. Excepteur Sint
3. Occaecat Cupidatat

Chronic urticaria

1. Non Proident
2. Sunt In
3. Culpa Qui
4. Officia Deserunt
5. Mollit Anim
6. Id Est
7. Laborum Lorem

2 DMX informs Statistician

Hello, my centre has:

- 10 pts with AR
- 7 patients with FA
- 3 patients with DA
- 10 patients with Asthma
- 3 pts with AD
- 7 pts with CU

3 Statistician provides the random list of patients' numbers to DMX

OK, I've check how many you need to recruit.

Please select the following:

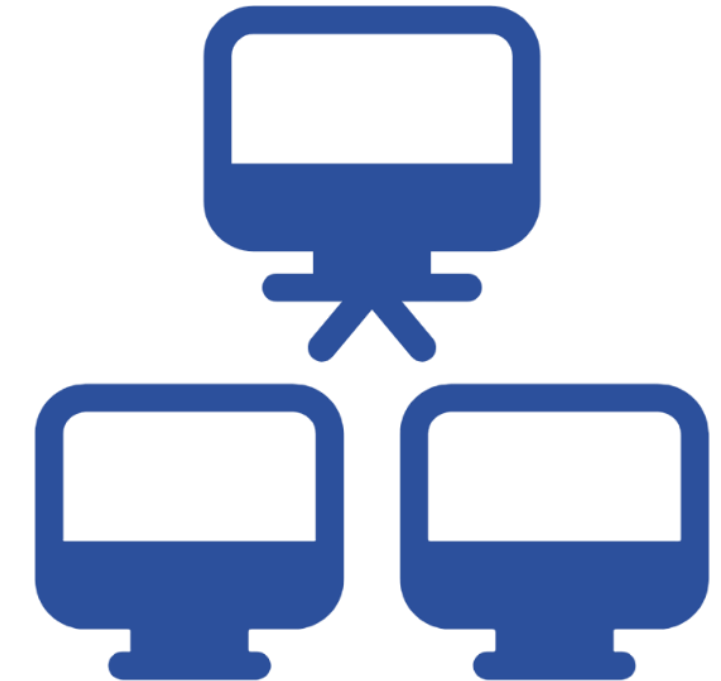
- for AR: 1, 3, 7, and 10
- for FA: 1 and 7
- for DA: select all
- for Asthma: 5, 7, 8, 10
- for AD: select all
- for CU: 2, 4, 5, 6

4 DMX collects data from the selected patients

Lorem Ipsum (AR and AD)
 Amet Consectetur (AR)
 Incididunt Ut (AR and FA and Asthma)
 Aliqua Ut (AR)
 Enim Ad (FA)
 Laboris Nisi (FA)
 Ut Aliquip (DA)
 Ex Ea (DA)
 Commodo Consequat (DA)
 In Reprehenderit (asthma)
 Velit Esse (asthma)
 Cillum Dolore (asthma)
 Nulla Pariatur (asthma)
 Excepteur Sint (AD)
 Occaecat Cupidatat (AD)
 Non Proident (CU)
 Sunt In (CU)
 Culpa Qui (CU)
 Officia Deserunt (CU)
 Mollit Anim (CU)
 Id Est (CU)
 Laborum Lorem (CU)

2 patients contribute to several AD, although they were selected for one of them only

Country	Centre	Patient
01 Austria	01 14	01 14
02 Belgium	02 15	02 15
03 Bulgaria	03 16	03 16
04 Czech Rep.	04 17	04 17
05 Lithuania	05 18	05 18
06 France	06 19	06 19
07 Germany	07 20	07 20
08 Italy	08 ...	08 ...
09 Poland	09 ...	09 ...
10 Romania	10 ...	10 ...
11 Serbia	11 ...	11 ...
12 Spain	12 ...	12 ...
13 Turkey	13 ...	13 ...



Patients identification details/personal data will not be shared outside the centre.

The technical team will provide a selection of numbers that will be used to identify patients

Patients will not be included with identifiable data

The IT platform is secure (password + encryption)

Protocol > Data anonymisation and safety

European regulations

General Data Protection Regulation
(GDPR)

National regulations

Ethics committee
application

Platform security

Data sharing

Individual centres

Good clinical
practices

Anonymised

Safe server

User/
password

Back-up

Contracts

Protocol > Data ownership and sharing

- Data will belong to EAACI who can agree, following MoUs, to share for specific secondary studies or analysis with NAS.
- Data sharing will comply with the international transfer restrictions set out in the standard-setting EU GPRD.
- When advised for the publication of results, datasets used may be made available for inspection in repositories.

Protocol > Research team and roles

Steering Committee	National coordinator	Centre coordinator	Centre researchers & data managers	Technical team (Inmusc)	External assessors
<ul style="list-style-type: none"> • Design of the registry protocol • Supervise all steps of the project • Inform all investigators • Lead primary publications • Provide sources of funding 	<ul style="list-style-type: none"> • Sign bilateral agreement with EAACI after review of the protocol • Attend project meetings and further inform all the other investigators • Present the registry to the investigators in the centres • Inform about the number, name and type of centres to the technical team • Provide the contact details of the centres • Identify problems in a timely manner and report to the technical team • Notify national regulatory authorities if needed • Notify national/ regional ethics committees 	<ul style="list-style-type: none"> • Seek approval by the local ethics committee • Identify the eligible patients (Excel list) • Communications with the technical team • Coordinate data collection in the centre • Custody of registry materials and collection of signatures • Report any problem to the national coordinator 	<ul style="list-style-type: none"> • Collect data • Contact patients • Enter data • Ensure data completeness and reliability 	<ul style="list-style-type: none"> • Protocol design • CRF and platform design • Monitoring • Analysis 	<ul style="list-style-type: none"> • Assessing the limitations, potential biases, and good practices.

Protocol > Publication Policy > Authorship rules – primary analysis of data

- Authorship rules are in agreement to ICMJE recommendations:
 - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
 - Drafting the work or revising it critically for important intellectual content; AND
 - Final approval of the version to be published; AND
 - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- In recognising that the contributors to the HEAD registry volunteer their time and expertise, authorship will be as inclusive as possible (i.e., all contributing investigators will be included), while always adhering to the ICMJE policy guidance without exception.

Protocol > Publication Policy > Secondary analysis of data

- NAS can always perform and publish additional analysis on the collected data registry:
 - A request with clear objectives and the protocol of the secondary analysis will be submitted to the Steering Committee
 - A separate MoU will be established
 - The NAS investigators performing the analysis will be the lead authors and NAS will establish the authorship according to the ICMJE rules

Questions on the protocol ?

Before entering data

Checklist I > Country level

- ✓ Is there a national coordinator?
- ✓ Have the protocol + materials been
 - Translated
 - Approved by the Ethics Committee (at least the centre of the coordinator)
- ✓ Are the data on centres accurate?
 - Total number of centres, names of centres, emails of contacts
 - Relevant: National figures (ratios)

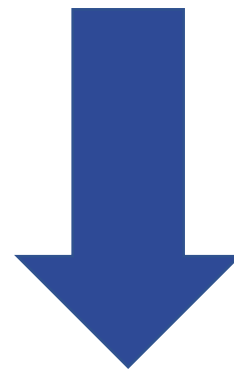
All national coordinators to report to the technical team and cross-check information



Checklist II > Centre level

- ✓ Has the centre been approved by the national coordinator?

- ✓ Has the centre obtained ethical approval?
 - If No → Obtain it*
 - If Yes →
 - Send a copy (1 per centre) of the approval to head-registry@inmusc.eu
 - cc National coordinator



In response to this email, the technical team will send the centre coordinator

REDCap survey link



*If not necessary, send the legal document needed to start in your centre signed.

REDCap Centres' survey



Participating Centres

Please complete the data in relation to the centre in the HEAD registry and all researchers that will provide data.

Thank you!

Page 1 of 1

Country
* must provide value

Centre name
* must provide value

Be careful with typing, as this is how the centre will appear in all places. Do not use ALL CAPS.

Resize font: [Returning?](#)

Please complete the data in relation to the centre in the HEAD registry and all researchers that will provide data.

Thank you!

If your country is not listed, contact head-registry@inmusc.eu

Country
* must provide value

Centre name
* must provide value

Be careful with typing, as this is how the centre will appear in all places.

Setting (Type of centre)

Type of administration

Click the next form to fill in the information of the researchers that will provide data in this centre. Fill in as many forms as researchers.

Submit

Save & Return Later

Powered by REDCap

Be careful typing centre name, as it is how it will appear everywhere. Do not use All caps. Only one centre.

Relevant for representativeness/sample size

By submitting you will be sent to the investigators' forms.

You can also save and return later (save the code)

Centres' data: Coordinator

If possible, only one coordinator per centre

These data refer to the centre coordinator, whose tasks are:

- Seek approval by the local ethics committee
- Identify the eligible patients (Excel list)
- Communications with the technical team
- Coordinate data collection in the centre and training
- Custody of registry materials and collection of signatures
- Report any problem to the national coordinator

Name of centre coordinator

* must provide value

Be careful with typing, as this is how it will appear in publications

Surname (last name) of researcher

* must provide value

Be careful with typing, as this is how it will appear in publications

e-mail

* must provide value

Date when the qualification for data entry of the centre was attained

If the coordinator did not attend a training session, he or she must contact head-registry@inmusc.eu as soon as possible

* must provide value

Today

0-0-0

The dates will be cross-checked with the attendance to the sessions

Affiliation/s (to appear in publications)

* must provide value

Expand

Be careful with typing, as this is how it will appear in publications

ORCID (to appear in publications)

If you are providing patients to the HEAD registry from more than one centre, please inform the registry managers at head-registry@inmusc.eu.

Submit and

- or -

This form can only be filled after having done the training. Please, contact the technical team at head-registry@inmusc.eu if you are a centre coordinator and did not attend a session

This information will be used in publications of the registry. Here you can add more than one centre.

If there are several centre coordinators in one centre, click on "Add another centre coordinator"

Centres' data: Data manager



EAACI
EUROPEAN ACADEMY OF ALLERGY
AND CLINICAL IMMUNOLOGY

If more than one person is entering data from the centre, please, fill as many forms as needed.

Name of data manager

* must provide value

Be careful with typing, as this is how it will appear in publications

Surname (last name) of data manager

* must provide value

Be careful with typing, as this is how it will appear in publications

e-mail

* must provide value

If this person changes during the conduct of the project, please, notify it at head-registry@inmusc.eu.

Submit and

- or -

A data manager is anybody who will enter data (researchers or technicians)

This information will be used to provide a user and password for the REDCap platform

If more than one person will be entering data in one centre, click on "Add another data manager"

Patients' selection (I)

- Send a list of eligible patients with disease for centralised stratified random sampling by the technical team:

- Create an Excel file with all the patients in the centre and the following columns:

Name of the patient	Code	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Drug allergy	Food allergy
Joseph Smith	1		X	X		X	
Anna Ripley	2	X					
...	3		X			X	

This will be the code for the informed consent

Check all the target diseases each patient has

- Make a copy of the file deleting the "Name" column → send to head-registry@inmusc.eu

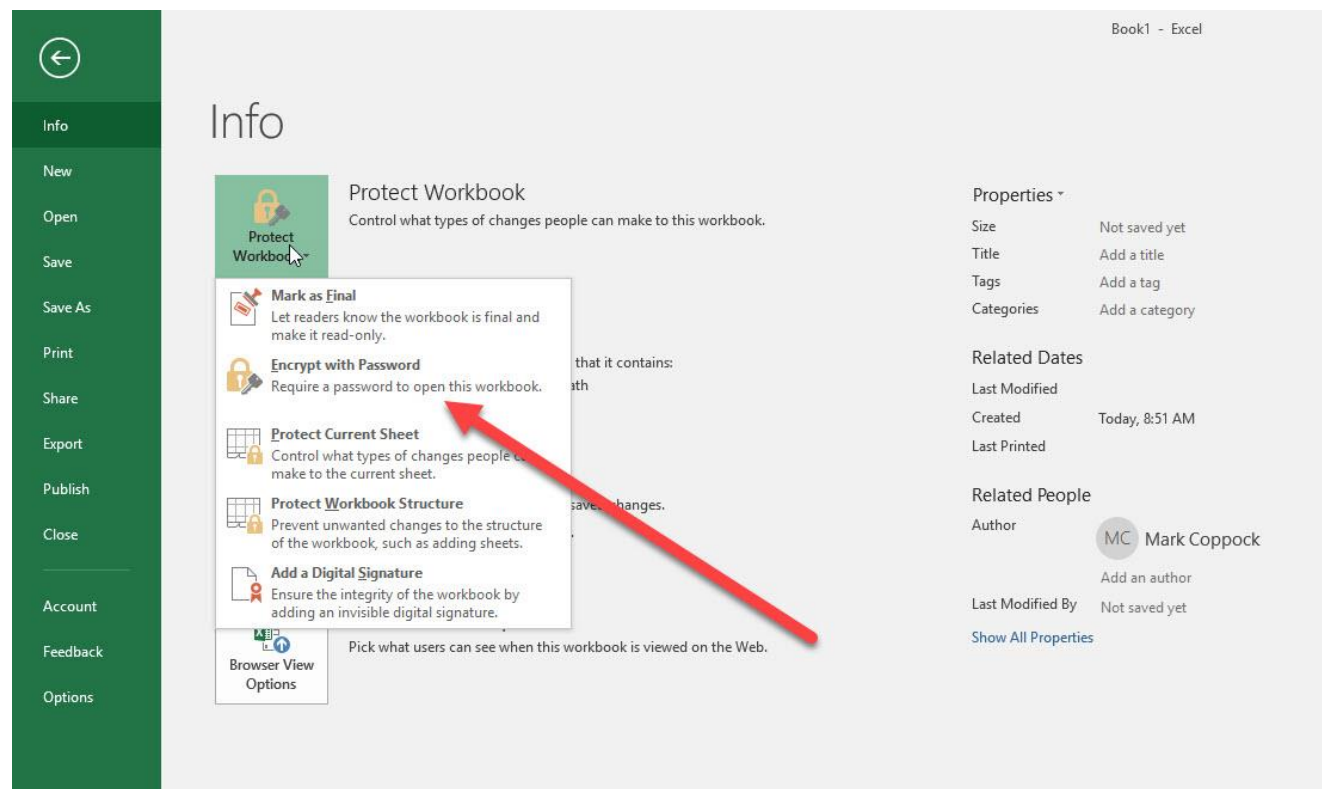
Code	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Drug allergy	Food allergy
1		X	X		X	
2	X					
3		X			X	

- Save the original Excel file protected

To protect an Excel file

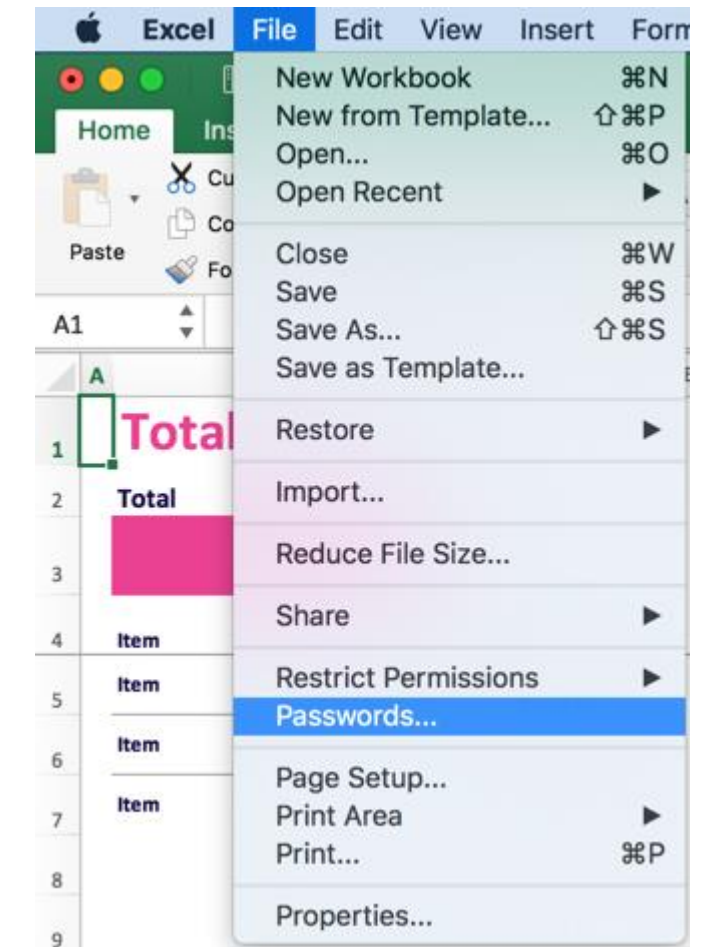
PC

1. Select File > Info.
2. Select the Protect Workbook box and choose Encrypt with Password.
3. Enter a password in the Password box, and then select OK.
4. Confirm the password in the Reenter Password box, and then select OK.



Mac

1. Open the MS Excel for Mac file you want to encrypt and password protect.
2. Select File > Passwords. ...
3. In the Password to open field, type a password. ...
4. Click OK. ...
5. Reenter the same password.
6. Click OK.



Patients' selection (II)

- The technical team will provide the list of selected patients:

- *“The following codes have been selected”:*

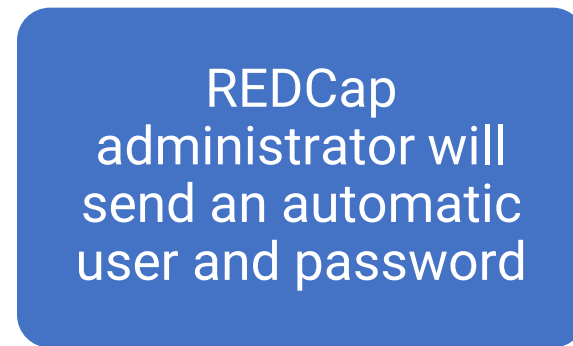
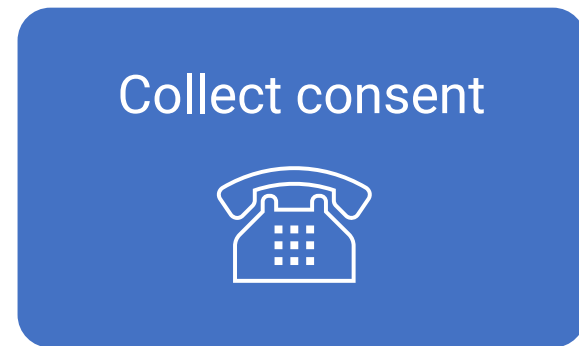
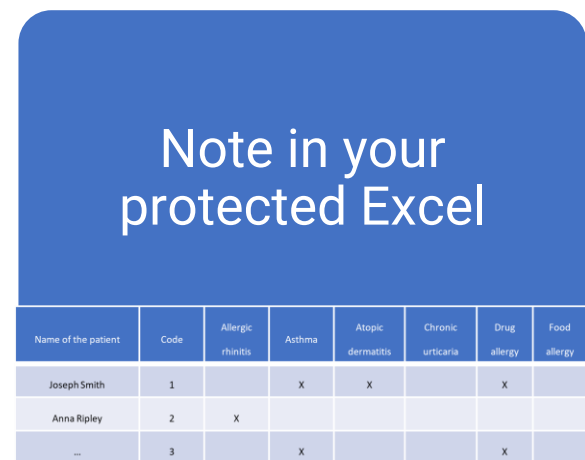
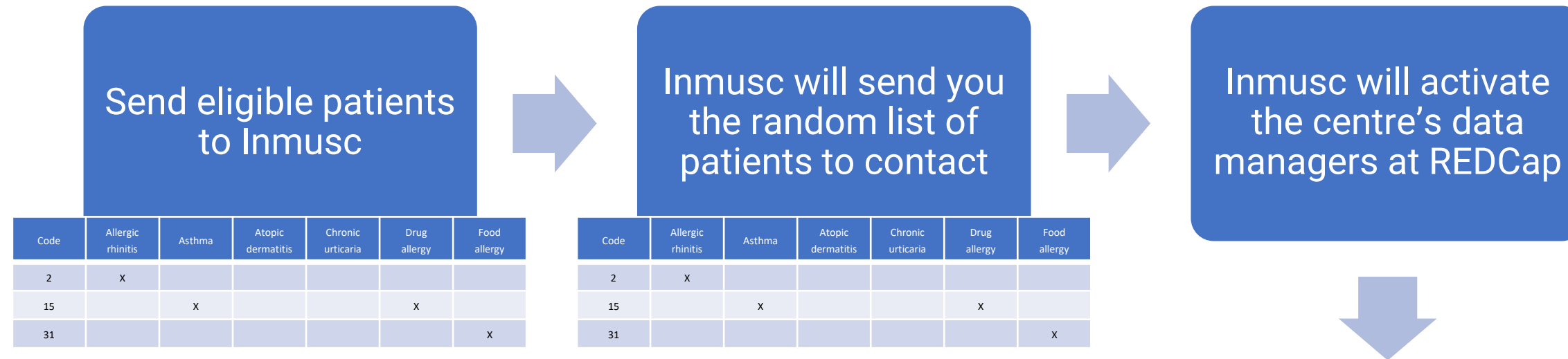
Code	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Drug allergy	Food allergy
2	X					
15		X			X	
31						X

- *“Keep these other codes as a **replacement** in case a patient declines participation”:*

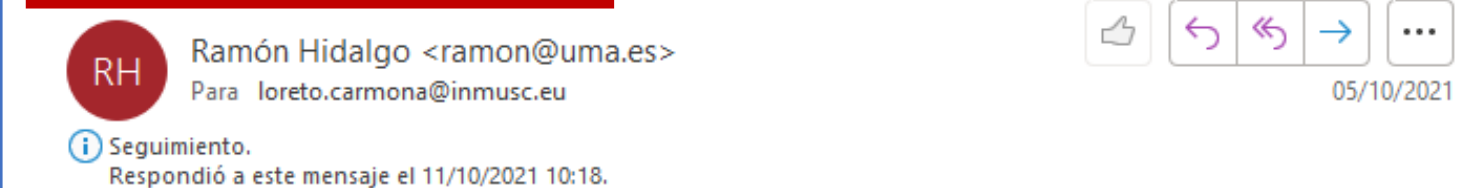
Code	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Drug allergy	Food allergy
4	X					
60		X			X	
58						X

- Find contact details of the selected patients to obtain consent and collect data.
- Note in your Excel the ones selected and the date you obtained consent (or this was declined)

Patients' recruitment (Centre coordinator)



REDCap access granted



RH Ramón Hidalgo <ramon@uma.es>
Para loreto.carmona@inmusc.eu

Seguimiento.
Respondió a este mensaje el 11/10/2021 10:18.

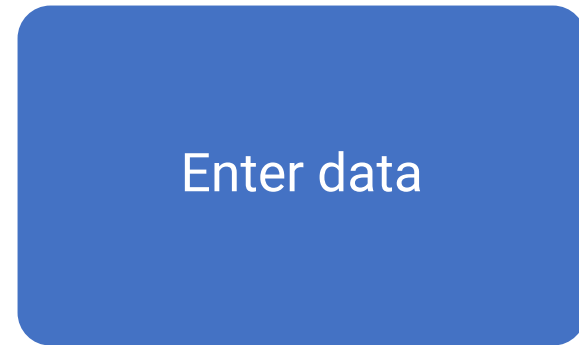
[This message was automatically generated by REDCap]

A REDCap account has been created for you in which your REDCap username is "loreto.carmona". Click the link below to set your new password and log in.

After logging in, please make sure to set up your password recovery question, which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you can also set it on your 'My Profile' page under 'Login-related options'.

[Set your new REDCap password](#)

Make sure you set your password before entering data



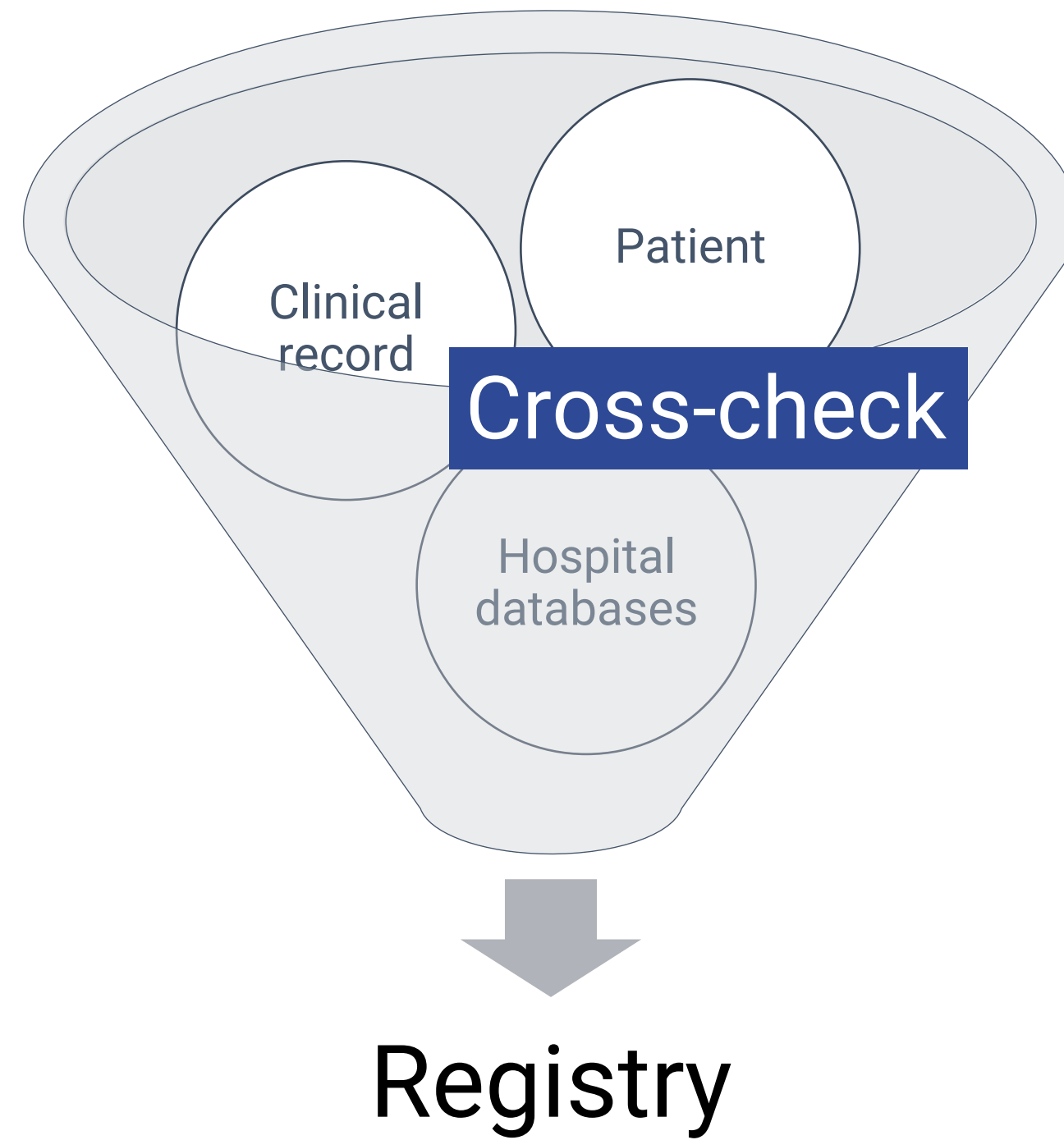
Informed consent + data collection (patient)

- Telephone call
 - (Pre-agreement)
 - → note in the clinical records
 - → signature at any moment when they attend the clinic
 - Provide the data or set a date for data collection
 - → Explain that data will be related to year 2019

Questions on checklist pre-data-entry and patient selection ?

Data sources and dates

Data sources



Dates

- Some data refer to EVER (ever been assessed or treated with)

- Most data will refer to a 12-month period
 - For hospital data and clinical records
 - Start fixing the last visit of the patient in 2019
 - Go backward 12 months and set the initial date of the observation period

 - For patient derived data
 - 2019 (tax year)

**Questions on data
sources or on how to fix
the observation period per
patient
?**

Entering data in REDCap

Entering in REDCap (Data managers)

- You will receive two emails from REDCap (redcap@uma.es)
- Make sure you open them in order.

De	Asunto	Recibido	Tamaño
redcap@uma.es	REDCap access granted	ju. 04/11/2021 11:40	6 KB
REDCap Administrator	REDCap password reset	ju. 04/11/2021 11:39	6 KB

REDCap access granted

redcap@uma.es
Para loreto.carmona@ser.es

[This message was automatically generated by REDCap]

A REDCap account has been created for you in which your REDCap username is "**loreto2**". Click the link below to set your new password and log in.

After logging in, please make sure to [set up your password recovery question](#), which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you can also set it on your Profile page under 'Login-related options'.

[Set your new REDCap password](#)

Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated Excel and common statistical project calendar, a scheduling features, such as branching logic.

Learn more about REDCap by would like to view other quick its features, please see the [Tr](#)

NOTICE: If you are collecting d review and approval of the pr

If you require assistance or h [REDCap Administrator](#).

REDCap Features

Build online surveys and databases quickly and securely in your bro
- Create and design your project using a secure login from any device. No software required. Access from anywhere, at any time.

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ible any time, even a
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- Use a list of email
ndents and automat
k who has responde
ass email mailings. t
app on a mobile devi
en later sync data ba
logic, and Missing Da
ata entry. Open data
ancies and other iss
nerating reports to vi
statistics and charts.
rt your data as a PD
Microsoft Excel.

Set Up Password Recovery Question

To help you easily and quickly recover your REDCap password (in case you forget it in the future), we need you to select a security question of your choice below and then provide an answer for it. Once you have filled out this information, if you forget your password, you can click the 'Forgot Your Password?' link on the REDCap login screen, and it will ask you to provide a correct answer to your security question (the one you will select below). In such a case, it will send a new temporary password to the email address associated with your REDCap account. Setting up your password recovery question below will prevent you from having to wait on a REDCap administrator to reset it manually if you ever forgot your password.

NOTICE: It is highly recommended that you set your password recovery question now, or else you might get accidentally locked out of your REDCap account.

Select a question:

Provide answer to question: (not case sensitive)

Please confirm your email address:
(If you attempt to recover your password, your new password will be sent to this email address.)

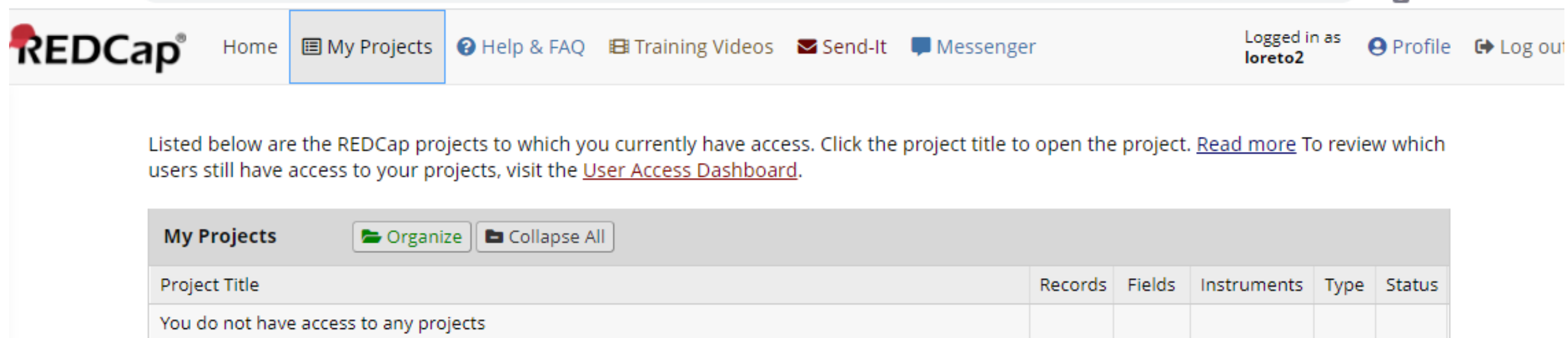
[Not now. Remind me again in 2 days.](#)

Secure file storage and sharing - Upload and share any type of file with anyone in the world through the File Repository feature or Send-It tool.

- You will be redirected to log in to set your password.
- The password must be 9 characters long and contain upper and lower case letters and numbers.
- They will also ask you to introduce a safety question to recover your password.

Entering in REDCap

- Once you have set your password, you're already in REDCap.
- Go to the upper band to My projects.



REDCap® Home **My Projects** Help & FAQ Training Videos Send-It Messenger Logged in as **loreto2** Profile Log out

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects [Organize](#) [Collapse All](#)

Project Title	Records	Fields	Instruments	Type	Status
You do not have access to any projects					

- In case it says “You do not have access to any projects”, send an email to head-registry@inmusc.eu



<https://redcap.uma.es/>

Log In

Please log in with your user name and password. If you are having trouble logging in, please contact [REDCap Administrator](#).

Username:

Password:

Log In

[Forgot your password?](#)

If you have problems, either contact REDCap administrator or head-registry

If you do not remember your password, click here

Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a [brief summary video \(4 min\)](#). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the [Training Resources](#) page.

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [REDCap Administrator](#).

REDCap Features

Build online surveys and databases quickly and securely in your browser - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

Fast and flexible - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.

Advanced instrument design features - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions.

Diverse and flexible survey distribution options - Use a list of email addresses or phone numbers for your survey respondents and automatically contact them with personalized messages, and track who has responded. Or create a simple link for an anonymous survey for mass email mailings, to post on a website, or print on a flyer.

Data quality - Use field validation, branching/skip logic, and Missing Data Codes to improve and protect data quality during data entry. Open data queries to automatically identify and resolve discrepancies and other issues real-time.

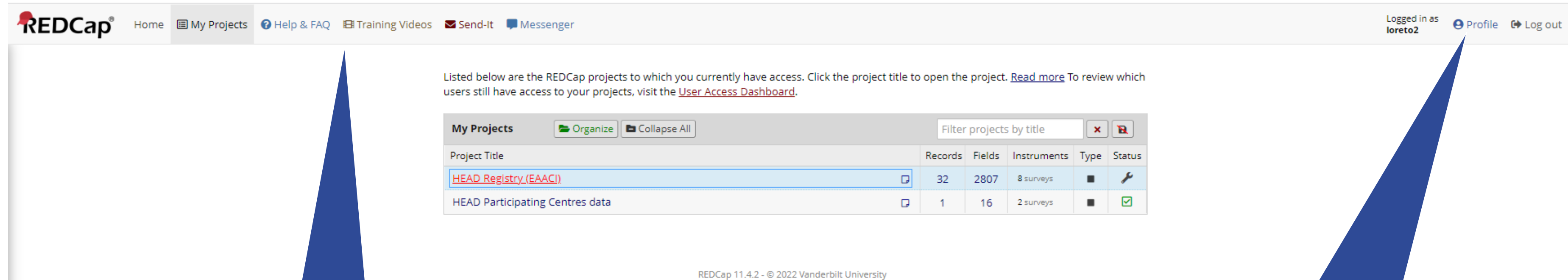
Custom reporting - Create custom searches for generating reports to view aggregate data. Identify trends with built-in basic statistics and charts.

Export data to common analysis packages - Export your data as a PDF or as CSV data for easy analysis in SAS, Stata, R, SPSS, or Microsoft Excel.

Secure file storage and sharing - Upload and share any type of file with anyone in the world through the File Repository feature or Send-It tool. Also works with exports and other built-in file uploading features.

Data-based triggers and alerts - Send real-time alerts and notifications to

Under “My projects” go to HEAD Registry (EACCI)



REDCap® Home My Projects Help & FAQ Training Videos Send-It Messenger

Logged in as **loreto2** Profile Log out

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects [Organize](#) [Collapse All](#) Filter projects by title

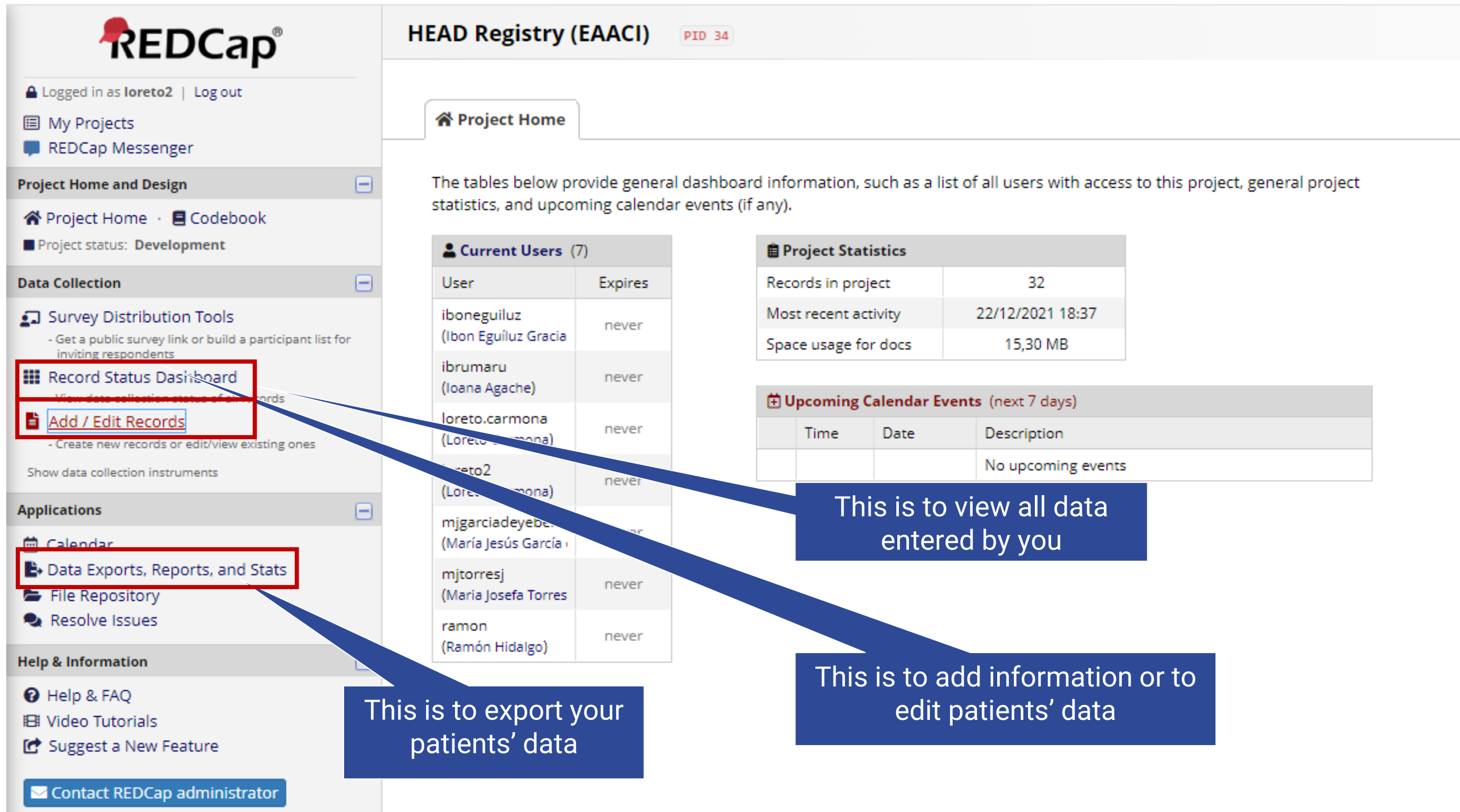
Project Title	Records	Fields	Instruments	Type	Status
HEAD Registry (EAACI)	32	2807	8 surveys	■	🔧
HEAD Participating Centres data	1	16	2 surveys	■	☑

REDCap 11.4.2 - © 2022 Vanderbilt University

REDCap training videos
and FAQs

You can always set in your
profile user's preferences

Then go directly to “Add New record / Edit” in the left column menu



The screenshot shows the REDCap interface for the HEAD Registry (EAACI) project. The left sidebar contains a navigation menu with several sections. Two items are highlighted with red boxes and callouts:

- Record Status Dashboard** (with a sub-item **Add / Edit Records**): This is to view all data entered by you.
- Data Exports, Reports, and Stats**: This is to export your patients' data.

The main content area displays project information and several tables:

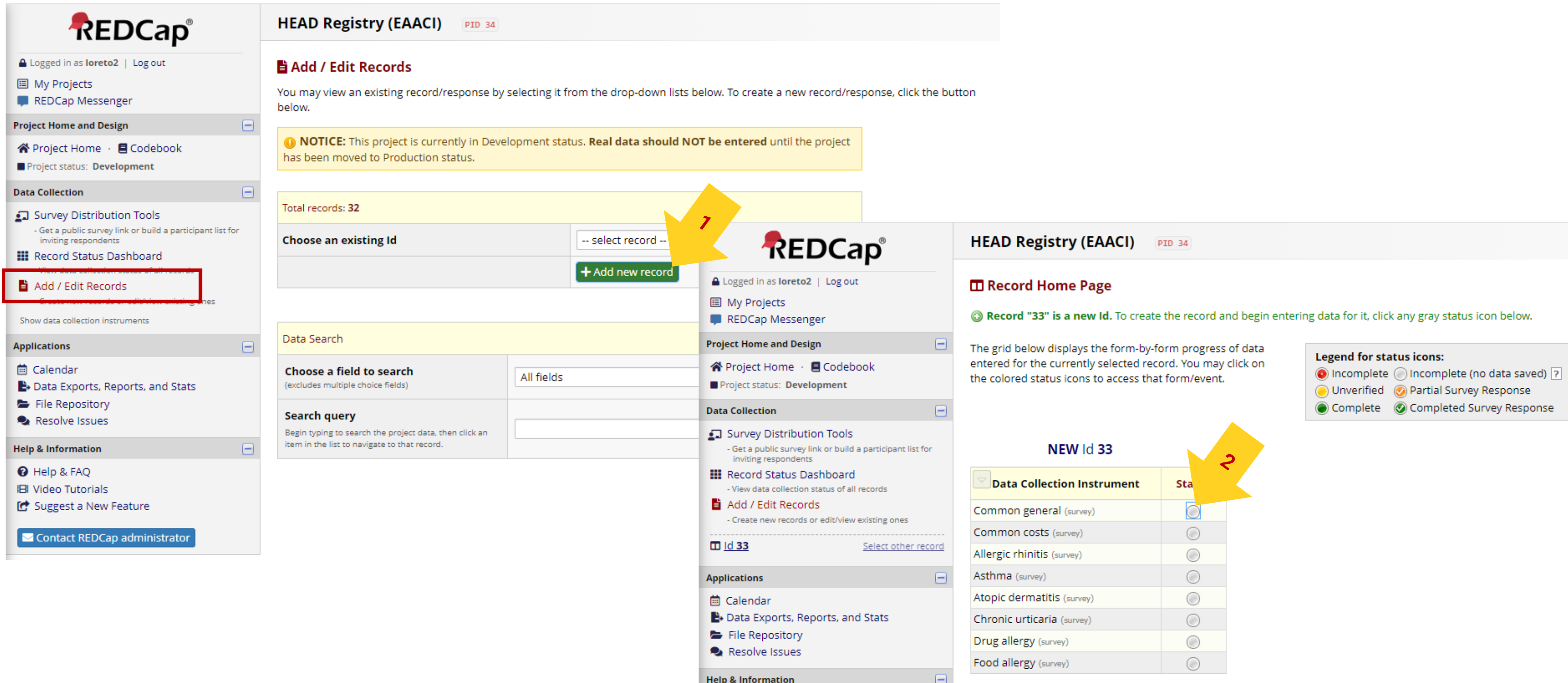
- Project Home**: The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).
- Current Users (7)**: A table listing users and their expiration dates.
- Project Statistics**: A table showing project metrics.
- Upcoming Calendar Events (next 7 days)**: A table showing no upcoming events.

User	Expires
iboneguiluz (Ibon Eguiluz Gracia)	never
ibrumaru (Ioana Agache)	never
loreto.carmona (Loreto Carmona)	never
loreto2 (Loreto Carmona)	never
mjgarcia de yebena (María Jesús García)	never
mjtorresj (Maria Josefa Torres)	never
ramon (Ramón Hidalgo)	never

Records in project	32
Most recent activity	22/12/2021 18:37
Space usage for docs	15,30 MB

Time	Date	Description
		No upcoming events

Add a new patient: Click on “Add New record” then on the grey button “Common general”



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My Projects

REDCap Messenger

Project Home and Design

Project Home · Codebook

Project status: **Development**

Data Collection

Survey Distribution Tools

- Get a public survey link or build a participant list for inviting respondents

Record Status Dashboard

Add / Edit Records

Show data collection instruments

Applications

Calendar

Data Exports, Reports, and Stats

File Repository

Resolve Issues

Help & Information

Help & FAQ

Video Tutorials

Suggest a New Feature

Contact REDCap administrator

HEAD Registry (EAACI) PID 34

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

NOTICE: This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.

Total records: 32

Choose an existing Id: -- select record --

+ Add new record

Data Search

Choose a field to search (excludes multiple choice fields): All fields

Search query:

Begin typing to search the project data, then click an item in the list to navigate to that record.

REDCap®

Logged in as loreto2 | Log out

My Projects

REDCap Messenger

Project Home and Design

Project Home · Codebook

Project status: **Development**

Data Collection

Survey Distribution Tools

- Get a public survey link or build a participant list for inviting respondents

Record Status Dashboard

- View data collection status of all records

Add / Edit Records

- Create new records or edit/view existing ones

Id 33 [Select other record](#)

Applications

Calendar

Data Exports, Reports, and Stats

File Repository

Resolve Issues

Help & Information

HEAD Registry (EAACI) PID 34

Record Home Page

Record "33" is a new Id. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:

- Incomplete
- Incomplete (no data saved)
- Unverified
- Partial Survey Response
- Complete
- Completed Survey Response

NEW Id 33

Data Collection Instrument	Status
Common general (survey)	<input type="radio"/>
Common costs (survey)	<input type="radio"/>
Allergic rhinitis (survey)	<input type="radio"/>
Asthma (survey)	<input type="radio"/>
Atopic dermatitis (survey)	<input type="radio"/>
Chronic urticaria (survey)	<input type="radio"/>
Drug allergy (survey)	<input type="radio"/>
Food allergy (survey)	<input type="radio"/>

For a better experience, select “Open Survey”

HEAD Registry (EAACI) PID 34

Actions: [Download PDF of instrument\(s\)](#) VIDEO: Basic data entry

Save & Exit Form
Save & Stay
-- Cancel --

Common general

Data Access Group: [No Assignment] ?

Invitation status: []

Survey options
Open survey
Log out + Open survey
Compose survey invitation
Survey Access Code and QR Code

Editing existing Id 31

Id 31

Centre name
* must provide value

Patient info

Patient code

Date of entry in the registry 10-01-2022 D-M-Y

Date when informed consent was obtained

Date of last visit (for an all-time visit) in 2019

Date of visit in 2018 (12 months before last visit)

Sociodemographic risk factors

Age (in 2019)

Gender

Higher educational level

It will open in a new page in the web-browser

You can download the pdf to fill it in paper and then go back to the platform

HEAD Registry (EAACI) | REDCap

Common general

Complete for all patients

Centre name
* must provide value
Azienda Sanitaria della Romagna
Start typing to find your centre name as provided

Next Page >>

Save & Return Later

Powered by REDCap

Fill in the dates and sociodemographic data

Common general


Resize font:
+ | -

Patient info

Patient code

Make sure the patient id is unique within your centre

Date of entry in the registry

10-01-2022  D-M-Y

Date when informed consent was collected

 D-M-Y

Date of last visit (for an allergic disease) in 2019

 D-M-Y

Date of visit in 2018 (12 months before)

 D-M-Y

<< Previous Page

Next Page >>

Save & Return Later

Sociodemographics and risk factors

Age (in 2019)

Gender

Higher educational level attained

Employment status

Smoking status

Occupational exposure

Yes

No

reset

Parental history of atopic disease

(asthma, allergic rhinitis, atopic dermatitis, food allergy, drug allergy, chronic urticaria, other)

Yes

No

reset

Has the patient reported symptoms to indoor or outdoor allergens

Yes

No

reset

Comorbidities

+ Autoimmune thyroid disease

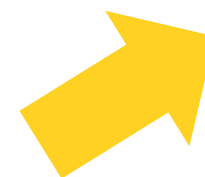
+ Chronic rhinosinusitis with nasal polyps

+ Chronic rhinosinusitis without nasal polyps

When "Yes" is selected, more information will be required

Fill in the dates and sociodemographic data

Occupational exposure	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
If yes	<input type="radio"/> In the past <input checked="" type="radio"/> Current	reset
Describe exposure	<div style="border: 1px solid #ccc; height: 80px;"></div>	Expand List allergens to which the patient is exposed at work
Parental history of any atopic disease (asthma, allergic rhinitis, atopic dermatitis, food allergy, drug allergy, chronic urticaria, other)	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Specify parental history of allergic disease	<div style="border: 1px solid #ccc; height: 80px;"></div>	Expand e.g., Mother: Asthma / Father: urticaria + atopic dermatitis, etc...
The patient has reported symptoms to indoor or outdoor allergens	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset



The patient has reported symptoms to indoor or outdoor allergens	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Specify allergens	<input checked="" type="checkbox"/> Pollens (specify) <input type="text"/>	
	<input checked="" type="checkbox"/> House dust mites	
	<input type="checkbox"/> Fungi <input type="text"/>	
	<input checked="" type="checkbox"/> Cat epithelial	
	<input checked="" type="checkbox"/> Dog epithelial	
	<input checked="" type="checkbox"/> Others (specify) <input type="text"/>	
Click all that apply		

Fill in the comorbidities

Comorbidities

- Autoimmune thyroid disease
- Chronic rhinosinusitis with nasal polyps
- Chronic rhinosinusitis without nasal polyps
- Gastroesophageal reflux disease
- Aspirin sensitivity
- Chronic obstructive pulmonary disease
- Contact dermatitis
- Obesity
- Malignancies
- Immunodeficiency
- Other chronic diseases (specify)


Click all that apply

[<< Previous Page](#) [Next Page >>](#)

[Save & Return Later](#)

In case of malignancy, immunodeficiency, and others, you will be prompted to specify

Check what allergic diseases the patient has.

Common general Resize font: 

Please indicate all allergic diseases (as per the inclusion criteria) currently present for this patient

	Yes	No	
Allergic rhinitis	<input type="radio"/>	<input checked="" type="radio"/>	reset
Atopic dermatitis	<input checked="" type="radio"/>	<input type="radio"/>	reset
Asthma	<input checked="" type="radio"/>	<input type="radio"/>	reset
Chronic urticaria	<input type="radio"/>	<input checked="" type="radio"/>	reset
Drug allergy	<input type="radio"/>	<input checked="" type="radio"/>	reset
Food allergy	<input checked="" type="radio"/>	<input type="radio"/>	reset

<< Previous Page
Submit
Save for Later

Make sure you mark "Yes" or "No" and then click on "Submit"

Close survey

Continue to fill form on costs

You can stop here and come back later with the return code or continue with the common cost or any other of the corresponding forms

📘 You may return to this survey in the future to modify your responses by navigating to the survey URL and entering the code below.

Return Code:

Download your survey response (PDF): 📄 Download

Survey Queue [Get link to my survey queue](#)

Listed below is your survey queue, which lists any other surveys that you have not yet completed. To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
Begin survey	Common costs
Begin survey	Asthma
Begin survey	Atopic dermatitis
Begin survey	Food allergy



Fill in the Costs form

Make sure you adjudicate costs to the right disease/s (write only in that cell). If the admission is caused by two diseases, count the same number of days

2 options:

- Enter the data directly in the form (preferred)
- Download an Excel file and upload it

You can get these data from the hospital database and or check with the patient

All costs refer to the 12-month interval (2018-2019)

Direct Costs
Fill in all admissions and visits during 2018-2019 in relation to allergic diseases.

	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Food allergy	Drug allergy
Number of hospitalisations						
ICU	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
General Ward	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Day hospital	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Length of stay (Days) - Add all admissions in the 12-month period						
ICU	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
General Ward	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of visits to...						
...emergency department	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
...specialist						
Allergist	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Pulmonologist	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Paediatrician	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Internal medicine specialist	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dermatologist	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
ENT surgeon	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
(Specify other)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
...Primary care	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
...psychologist	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Indirect Costs
Fill in all costs to the patient and society during 2018-2019 in relation to allergic diseases.

	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Drug allergy	Food allergy
Societal impact						
Missed workdays	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Missed school days	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Days lost by family members	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Disability pension in 2018-19	<input type="radio"/> Yes <input type="radio"/> No reset	<input type="radio"/> Yes <input type="radio"/> No reset	<input type="radio"/> Yes <input type="radio"/> No reset	<input type="radio"/> Yes <input type="radio"/> No reset	<input type="radio"/> Yes <input type="radio"/> No reset	<input type="radio"/> Yes <input type="radio"/> No reset
Work impairment (0-10)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
School performance impairment (0-10)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Individual impact						
Consultations paid out-of-pocket	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Medications paid out-of-pocket	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Private insurance not reimbursed	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Costs for environmental control at home (Specify below)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Specify environmental costs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cost for avoidance (special diet, special kindergarten, etc.)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Costs of transportation to the specialised centre	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other out-of-pocket expenses due to the allergic disease/s. Specify below:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Specify other out-of-pocket expenses	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

For these data you will need to contact the patient. Let him/her know in advance what you will ask


Fill in the Costs form

- 2 options:
 - Enter the data directly in the form (**preferred**)
 - Download an Excel file and upload it

Download Excel file to facilitate data collection

1. Download the Excel file (You can use this template for all patients in your centre).
2. Fill in the patient costs in 2018-19 (You will need to contact the patient).
3. Save the file naming it with the patient code (e.g., 021.xls).
4. Upload below.

Download the Excel file

Attachment:  [Costs.xlsx](#) (0.02 MB)

188) Upload the Excel file [Upload file](#)

You can also download the Excel file (same cells than in the platform), complete it, and then upload it.

Choose only one option!

Continue with the forms missing

Close survey

Now complete all other forms related to specific variables by disease.

If a form opens and the patient does not have that allergic disease, scroll down and click on Complete.

☰ Survey Queue

🗨️ Get link to my survey queue

Listed below is your survey queue, which lists any other surveys that you have not yet completed.
To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
✔ Completed	Common costs
Begin survey	Asthma
Begin survey	Atopic dermatitis
Begin survey	Food allergy


In all disease forms you will be asked the dates of diagnosis, onset of symptoms, and who made the diagnosis

Fill in only if the patient has asthma

As defined by **at least one** of the following criteria:

1. Clinician-diagnosed asthma
2. Asthma symptoms or current use of asthma medication(s)
3. Recurrent wheezing
4. Wheezing apart from a cold

Date of onset of symptoms

  D-M-Y

If month is unknown enter 06. If day is unknown, enter 15

Date of diagnosis of asthma

(As defined by the entry criteria)

  D-M-Y

If month is unknown enter 06. If day is unknown, enter 15

Who made the diagnosis

- Allergist
- Pulmonologist
- Paediatrician
- Internal Medicine specialist
- Primary care physician
- ENT surgeon

Other

Click all that apply

Remember the criteria

If you click on the calendar icon you will have to scroll back to the year. It is faster to type it like this: 10-01-2021. Even if you type it like 10-1-21 or like 10/1/21 it will come out right

If you only know the year, select 15/06 of that year. If you know the month and year, select day 15th of that month

Then some specificities...

Control of asthma symptoms according to GINA 2021 criteria

Criteria	At the 2018 visit		At the 2019 visit	
	Yes	No	Yes	No
Daytime asthma symptoms more than twice/week?	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Any night awakening due to asthma?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Need of reliever/rescue treatment more than twice/week?	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Any activity limitation due to asthma?	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

For asthma is whether the patient was controlled according to the GINA criteria in the 2018 and the 2019 visits

Culprit food/s

Expand

For drug and food allergies is culprit drugs or food/s

AR characterisation (ARIA criteria)

ARIA criteria

Intermittent symptoms

- <4 days per week
- Or <4 weeks

Persistent symptoms

- >4 days per week
- And ≥4 weeks

Mild

- No impairment of sleep
- No impairment of daily activities, sport, leisure
- No impairment of work and school
- No troublesome symptoms

Moderate/Severe One or more items

- Abnormal sleep
- Impairment of daily activities, sport, leisure
- Impaired work and school
- Troublesome symptoms

By duration

- Intermittent
- Persistent

By severity

- Mild
- Moderate-Severe

Disease control by VAS (0-10) (Physician's opinion)

Current

(Last visit in 2019)

0 1 2 3 4 5 6 7 8 9 10

reset

Baseline

(First visit in 2018)

0 1 2 3 4 5 6 7 8 9 10

reset

For allergic rhinitis is ARIA criteria and VAS

Next is diagnostic tests:

1) EVER, then, if checked 2) number done in 2018-19

Diagnostic tests for asthma

Indicate whether the following diagnostic procedures have ever been performed during the patient history to diagnose asthma.

When a test is selected, new lines will open to provide the number of times the diagnostic test was done in the 12-month time interval.

- Spirometry
- Bronchodilator testing
- Airway hyperreactivity test (e.g., methacholine testing)
- Exhaled NO
- IOS
- Body plethysmography
- Skin prick tests
- Serum total IgE
- Serum specific IgE
- Component-resolved diagnosis in serum (molecular allergens)
- Blood eosinophils
- Sputum cellularity
- Chest X-rays
- HRCT
- Microbiology tests
- Therapeutic trial with corticosteroids
- Other tests

Click all that apply

Number of serum total IgE tests done for asthma in 2018-2019	<input type="text"/>
Number of sputum cells counts done for asthma in 2018-2019	<input type="text"/>

Indicate only how many were done in the observation period. This will open automatically if marked above (Ever)

Then pharmacological interventions in 2018-19 period

Pharmacological interventions for asthma

Indicate whether the following interventions have been used for this patient for the management of asthma between 2018 (baseline) and 2019 (12-month period).

When an intervention is selected, new lines will open to provide specifications.

- ICS
- LABA
- Ultra-LABA
- ICS-LABA
- ICS-ultra LABA
- LAMA
- ICS-LABA-LAMA
- LABA-LAMA
- Ultra LABA-LAMA
- LTRA
- Biologicals
- OCS as controller (outside an exacerbation)
- SCIT
- SLIT
- Vaccination (flu vaccine, etc.)
- Others

Once you click on a product, you'll be prompted to provide commercial name, dose, frequency and duration

Ultra-LABA-LAMA

Commercial name (All caps)	Dose (mcg/intake)	Frequency	Duration (days)
<input type="text"/>	<input type="text"/>	<input type="text" value="v"/>	<input type="text"/>

Biological

Commercial name (All caps)	Dose (mg)	Frequency	Duration (days)
<input type="text"/>	<input type="text"/>	<input type="text" value="v"/>	<input type="text"/>

SCIT

Where was it administered? (Check all that apply)	Total number of doses
<input type="checkbox"/> hospital <input type="checkbox"/> outpatient clinic <input type="checkbox"/> primary care <input type="checkbox"/> other	<input type="text"/>

If marked, you'll need to specify name (ALL CAPS), and dose (mcg or mg, depending on the drug) , frequency and days used in 2018-19

Some interventions have other specifications

The last part relates to exacerbations/flare-ups

Severe asthma exacerbations

Defined as by **at least one** of the following:
 1) Use of systemic corticosteroids or an increase from a stable maintenance dose, for at least 3 days.
 2) A hospitalisation or emergency department visit because of asthma, requiring systemic corticosteroids.

Number of asthma exacerbations during the 12-month period

1st exacerbation in 2018-19

Treatments used	Procedures or devices
<input type="checkbox"/> Oral corticosteroids <input type="checkbox"/> Parenteral corticosteroids <input type="checkbox"/> Antibiotics <input checked="" type="checkbox"/> Inhaled bronchodilators <input type="checkbox"/> Intravenous bronchodilators <input type="checkbox"/> ICS <input type="checkbox"/> Mucolytics <input type="checkbox"/> Oxygen <input type="checkbox"/> Others	<input type="checkbox"/> Nebulisation <input checked="" type="checkbox"/> Holding chamber (spacer) <input type="checkbox"/> Intubation <input type="checkbox"/> Other

When an intervention is selected, new lines will open to provide specifications

Inhaled bronchodilators

Commercial name (All caps)	Dose (mcg/intake)	Frequency	Duration (days)
<input type="text"/>	<input type="text"/>	<input type="text" value="v"/>	<input type="text"/>

2nd exacerbation in 2018-19

Treatments used	Procedures or devices
<input type="checkbox"/> Oral corticosteroids <input checked="" type="checkbox"/> Parenteral corticosteroids <input type="checkbox"/> Antibiotics <input checked="" type="checkbox"/> Inhaled bronchodilators <input type="checkbox"/> Intravenous bronchodilators <input type="checkbox"/> ICS <input type="checkbox"/> Mucolytics <input checked="" type="checkbox"/> Oxygen <input checked="" type="checkbox"/> Others	<input type="checkbox"/> Nebulisation <input type="checkbox"/> Holding chamber (spacer) <input type="checkbox"/> Intubation <input type="checkbox"/> Other

When an intervention is selected, new lines will open to provide specifications

For asthma, atopic dermatitis, and chronic urticaria is exacerbations/flare-ups in 2018-19. For each exacerbation/flare you will have to indicate treatment used and specifications

For food allergy it will ask about lifetime episodes and then specifications about those that occurred in 2018-19, including severity and culprit food

Total number of grade 3-5 episodes (lifetime)
For each reaction, specify severity and treatment below

Total number of grade 3-5 episodes 2018-19
For each reaction, specify below severity and treatment used.

1st reaction (2018-19) Specifications

Culprit food	Severity	Treatment used in the reaction
<input type="text"/>	Grade 3 v	<input type="checkbox"/> Adrenaline iv <input type="checkbox"/> Adrenaline im administered by a health care provider <input type="checkbox"/> Adrenaline im administered by autoinjector <input type="checkbox"/> Corticosteroids oral <input type="checkbox"/> Corticosteroids parenteral <input type="checkbox"/> Antihistamines oral <input checked="" type="checkbox"/> Antihistamines iv <input type="checkbox"/> Bronchodilators inhaled <input type="checkbox"/> Bronchodilators iv <input type="checkbox"/> Fluids iv <input type="checkbox"/> Others

Antihistamines

Commercial name (All caps)	Dose (mg/intake)	Frequency	Duration (days)
<input type="text"/>	<input type="text"/>	<input type="text" value="v"/>	<input type="text"/>

The last part relates to exacerbations/flare-ups

Total number of episodes of drug allergic reactions (lifetime) For each reaction fill data below (Up to 10 reactions. if more, fill in for the latest 10)

1st lifetime reaction - Specifications

Year	Culprit drug	Temporality	Severity	Treatment used
<input type="text"/>	<input type="text"/>	immediate	Grade 2	<input type="checkbox"/> Adrenaline iv <input type="checkbox"/> Adrenaline im <input type="checkbox"/> Corticosteroids oral <input type="checkbox"/> Corticosteroids parenteral <input type="checkbox"/> Antihistamines oral <input type="checkbox"/> Antihistamines iv <input type="checkbox"/> Bronchodilators inhaled <input type="checkbox"/> Bronchodilators iv <input type="checkbox"/> Fluids iv <input type="checkbox"/> Others

2nd lifetime reaction - Specifications

Year	Culprit drug	Temporality	Severity	Treatment used
<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/> Adrenaline iv <input type="checkbox"/> Adrenaline im <input type="checkbox"/> Corticosteroids oral <input type="checkbox"/> Corticosteroids parenteral <input type="checkbox"/> Antihistamines oral <input type="checkbox"/> Antihistamines iv <input type="checkbox"/> Bronchodilators inhaled <input type="checkbox"/> Bronchodilators iv <input type="checkbox"/> Fluids iv <input type="checkbox"/> Others (specify)

3rd lifetime reaction - Specifications

Year	Culprit drug	Temporality	Severity	Treatment used
<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/> Adrenaline iv <input type="checkbox"/> Adrenaline im <input type="checkbox"/> Corticosteroids oral <input type="checkbox"/> Corticosteroids parenteral <input type="checkbox"/> Antihistamines oral <input type="checkbox"/> Antihistamines iv <input type="checkbox"/> Bronchodilators inhaled


For drug allergy it will ask about lifetime episodes and then specifications about these with year, temporality, and severity

Once you're done with all forms, close survey

Close survey

Review the forms or exit

Survey Queue


 [Get link to my survey queue](#)

Listed below is your survey queue, which lists any other surveys that you have not yet completed.
To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
✓ Completed	Common costs
✓ Completed	Asthma
✓ Completed	Atopic dermatitis
✓ Completed	Food allergy

Dashboard

- You can check all the patients entered by you and whether the forms are completed or not.
- By clicking on any red dot you're directed to the form in that specific patient.



Logged in as loreto2 | Log out

My Projects
REDCap Messenger

Project Home and Design

Project Home · Codebook
Project status: Development

Data Collection

Survey Distribution Tools
- Get a public survey link or build a participant list for inviting respondents

Record Status Dashboard

Add / Edit Records
- Create new records or edit/view existing ones

Show data collection instruments

Applications

Calendar
Data Exports, Reports, and Stats
File Repository
Resolve Issues

Help & Information

Help & FAQ
Video Tutorials
Suggest a New Feature

Contact REDCap administrator

HEAD Registry (EAACI) PID 34

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] v

Displaying Data Access Group -- ALL -- v

Displaying record Page 1 of 1: "1" through "32" v of 32 records ALL (32) v records per page

[+ Add new record](#)

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Id	Common general	Common costs	Allergic rhinitis	Asthma	Atopic dermatitis	Chronic urticaria	Drug allergy	Food allergy
1	✓	✓	✓	●	●	✓	✓	●
2	●	●	●	●	●	●	●	●
3	●	●	●	●	●	●	●	●
4	●	●	●	●	●	●	●	●
5	●	●	●	●	●	●	●	●
6	●	●	●	●	●	●	●	●
7	●	●	●	●	●	●	●	●
8	●	●	●	●	●	●	●	●
9	●	●	●	●	●	●	●	●
10	●	●	●	●	●	●	●	●
11	●	●	●	●	●	●	●	●
12	●	●	●	●	●	●	●	●
13	●	●	●	●	●	●	●	●
14	●	●	●	●	●	●	●	●
15	●	●	●	●	●	●	●	●
16	●	●	●	●	●	●	●	●
17	●	●	●	●	●	●	●	●

Others

Click all that apply

If you think something important was not collected in the CRF, please, explain here

Form Status

Complete? Incomplete v

Incomplete

Incomplete

Unverified

Complete

-- Cancel --

[Save & Stay](#)

If they are completed by survey you will not be able to edit
If you fill the forms by clicking on the buttons, then you'll be able to edit until finished (When you're done, click on "Finished")

Questions on how to enter data in REDCap ?

Monitoring

Monitoring

- Consistency
 - Central platform for data entry
 - Training
- Completeness
 - Each one to check for data quality
 - Alerts on entry forms with warning about missing data
- Accuracy
 - Cross-checking random samples



How will it be done?

- By-weekly we will download the database and check for inconsistencies or missing data
- We will contact centres as we encounter problems
 - Directly by e-mail, specifying the problem (centre coordinator)
 - With messages in the database (data managers)

Questions on monitoring ?

Updates

Frequency and format

- Monthly meetings with national coordinators
- Monthly newsletters (e-mail) including:
 - Update and benchmarking
 - Meetings resolutions

Questions ?



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