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Creating a New Project

Log in to the UH REDCap system https://redcap.helsinki.fi/

Create a new blank project with the title "Emollient for atopic eczema".

Select "Practice / Just for fun" as the project purpose.

Project settings

Enable Use surveys and Use longitudinal data collection with defined events



Data Collection Instruments

In this project we'll create instruments for baseline data, severity of symptoms and participant survey

Baseline Data

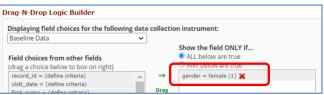




- 4. Add a field by clicking **Add Field** in the desired location.
- 5. Select a field type from the dropdown menu. Review and set each field attribute. Then click **Save**.

Field Label	Field Type	Notes	
1. Record ID	Text Box	Validation: Integer	
2. First Name	Text Box	Identifier, Required	
3. Last Name	Text Box	Identifier, Required	
4. Email	Text Box	Validation: Email, Required	
5. Visit Date	Text Box	Validation: Date (D-M-Y),	
		Required	
6. Gender	Multiple Choice - Radio Buttons	Required;	
	(Single Answer)	female	
		male	
		other	
7. Pregnancy Status	Multiple Choice - Radio Buttons	Required;	
	(Single Answer)	pregnant	
		not pregnant	
		unknown	
		Use branching logic to make	
		this field available when Gender	
		= "female"	





To test, go to Add / Edit Records and add your own information to the Baseline Visit.



Severity of Symptoms

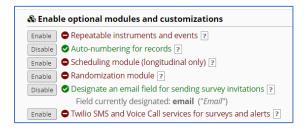
- 1. Go to Online Designer.
- 2. Click + Create a new instrument from scratch. Then click + Add instrument here.
- 3. Type the instrument name "Severity of Symptoms" and click Create.
- 3. Click the instrument name to edit it.
- 5. Add a field by clicking **Add Field** in the desired location.
- 6. Select a field type from the dropdown menu. Review and set each field attribute. Then click Save.

Field Label	Field Type	Response Options
Symptoms severity score	Multiple Choice - Radio Buttons	Required,
	(Single Answer)	Score
		0 None, absent
		1 Mild (just perceptible)

	2 Moderate (obvious)
	3 Severe

Participant Survey

- 1. Go to Designer.
- 2. Click + Import. Search for "participant survey".
- 3.Click on "Research Participant Perception Survey UP"
- 4. Click Import into my RedCap project.
- 5. Read and agree with the terms of use and Add
- 6. Go to the project settings and enable Designate an email field for sending survey invitations



7. Go to Designer.

Beside "the Research Participant Perception Survey – UP", click **Enable** on **Enabled as survey**. A Set Up My Survey tab will open.



Defining Events

- 1. Go to Project Setup
- 2. Click Define My Events.
- 3. Edit Event 1 name to Baseline Visit
- 4. Add three new events
 - Month 1 Visit
 - Month 2 Visit
 - Final Participant Survey



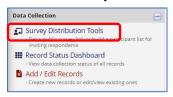
- 5. Click Designate Instruments for My Events.
- 6. Click Begin Editing. Check the appropriate boxes for each instrument. Then click Save.



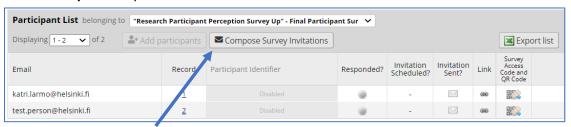


Distributing Survey

1. Click on Survey Distribution Tools (on the left)

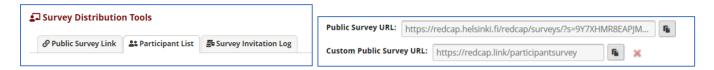


2. On Participant List you will see all the email addresses from the Baseline Visit email field.



- 3. Click Compose Survey Invitations.
- 4. Edit the text in the Compose box and review the message settings. Click Send Invitations.

NOTE: there is also a possibility for public survey link. If you prefer that the survey needs to be **the first instrument** and **first event** of the project.



User Rights

- 1. In the left menu click on User Rights.
- 2. Enter the user's REDCap username or email address in the top box and click Add with custom rights.
- 3. Select No Access to export data. Review all other settings and then click Add user.

Tip: If you have many users who need the same level of access, you can create a named role with defined rights. You can then assign new users to this role.

Adding, Viewing and Exporting a Record

Adding a Record

- 1. Click on Add / Edit Records.
- 2. Click + Add new record.
- 3. Click the status icon beside the first data collection instrument to begin editing the record.
- 4. Enter data into each form as if you were a study participant.
- 5. When you have tested all fields on a form, save and exit.

Viewing a Record

- 1. Click on Add / Edit Records.
- 2. **Choose a record ID** that you want to check.

Exporting Data

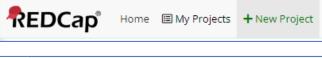
- 1. In the left menu click **Data Exports, Reports, and Stats**.
- 2. Click Export Data.

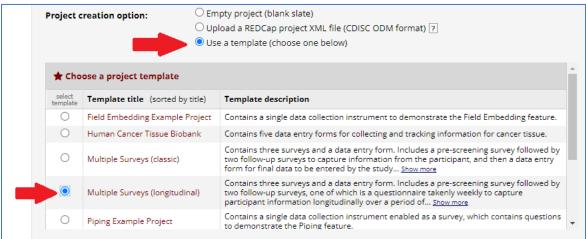


3. Review the possible formats, de-identification options, and advanced data formatting options. Choose the "CSV/Microsoft Excel (raw data)" format. Then click Export Data.

Using project templates, e.g. "Multiple Surveys (longitudinal)"

Create a new project, using REDCap template "Multiple Surveys (longitudinal)"





You will get a ready template, with some data collection instruments and defined events that you can further develop to meet your needs.

extra: Repeating Instruments

Enabling "Repeatable Instruments" allows you to collect multiple instances of the same data; an unlimited number of times without having to specify the amount needed. E.g. data from medication adverse events or repetitive surveys (weekly etc.)

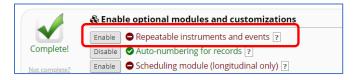
Create an instrument called Adverse Effect

Field Label	Field Type	Notes	
1. What is the symptom	Text Box	Field note: only adverse effect /	
		instrument	
2. Date the symptom started	Text Box	Validation: Date (D-M-Y),	
		Required	

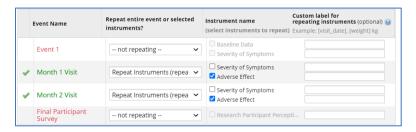
Go to Designate Instruments for My Events and assign Adverse Effects instrument for Month 1 and Month 2 visits.



Enable Repeatable instruments and events



Allow repeating the Adverse Effect instrument



Now you can get each adverse effect to its own form.



extra: Randomization

NOTE: RedCap does not create randomization. The **randomization table has to be generated outside of RedCap**, using other software (e.g. SAS, Stata, R) (Help for creating randomization: Biostatistics unit).

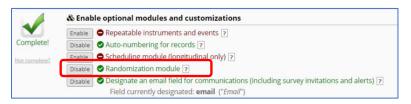
RedCap helps you implement a defined randomization model within your RedCap project.

1. Go to Baseline Data and add a field called Randomization Group

Field Label	Field Type	Notes
Randomization Group	Multiple Choice - Radio Buttons	variable: random_group
	(Single Answer)	Required;
		Choices:
		placebo
		intervention

2. Enabling the Randomization Model

Click on Enable Randomization module under the "Enable optional modules and customizations."



3. User Rights

Go to user rights and give yourself rights for randomization.



User rights for randomization:

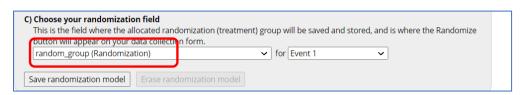
- Setup (setup the randomization)
- Dashboard (view the used randomization numbers)
- Randomize (perform the randomization of participants)

Be sure the user who sets up the randomization can be unblinded to the randomization (usually a statistician or data analyst, not the PI or coordinator).

4. Now you can start setting up the randomization, by clicking Randomization on the left panel.



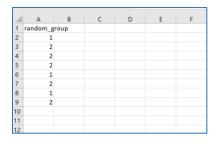
5. Choose your Randomization Field



6. Upload your randomization table as a cvs file.

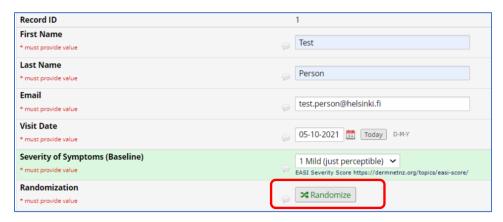


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7. Add a record to Baselin Data => click on Randomize and the participant will be randomized.



Note: The allocation table used in Development status **cannot be exactly the same as the allocation table used in Production status**. The allocation table in Development status is only used for testing of you project.



extra: Multiple Arms

Arms represent different sequences of assessments or treatments undertaken by the study participants. E.g.

- The intervention group may have a different study visit schedule from the control group.
- Separate arms for the **pediatric patients** and for their **caregivers**, e.g. when studying their experiences
- Multi-site studies

Notes: Differences between REDCap arms and traditional study arms?

- REDCap does not link the randomization module to arms. If randomization to an arm is required, the
 assignment to the study arm must be performed manually during data entry. See more on randomization
 and arms e.g. https://youtu.be/aVe6lpiRHtc video by Lead Data Intelligence Analyst Edward Kowalewski,
 Cedars-Sinai Health Services
- Normally a participant would be assigned to a single study arm. However, REDCap allows a participant ID to be present in each arm simultaneously. REDCap displays a warning if a participant ID is present in more than one arm.
- 1) Go to **Define my events**
- 2) Rename Arm 1 to Study Site1
- 3) Add a New Arm and rename it as Study Site 2. Define events and instruments for the Study Site 2.

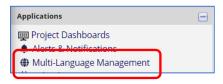




extra: Multi-Language Management

Notices:

- Instead of using "Multi-Language Management", you can simply create identical projects, just with different languages.
- If you use imported instruments from the REDCap shared library, remember to ask the permission for editing/translations.
- 1) Go to Multi-Language Management (on the left column)



2) Click "Add a new language" by "creating the language from scratch"



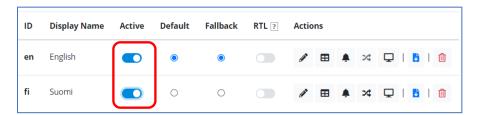
3) Give Language ID: en and Language Display Name: English



4) Add another langue: from available system languages => suomi.

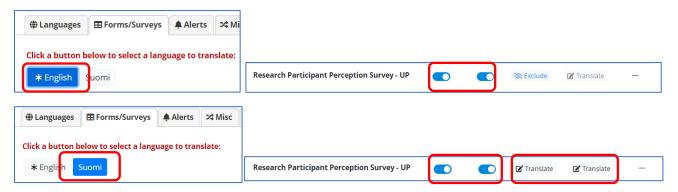


5) Set both languages as active.



6) Set the Research Participant Perception Survey to be translated, both in "English" and "Suomi"

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7) Translate on "Suomi" "Fields" and "Survey Settings" and provide the additional translations, if necessary. Remember to save changes.



8) NOTE: The Finnish "system languages" translation is not complete in all the fields, so you might want to check the "User Interface" translation also.

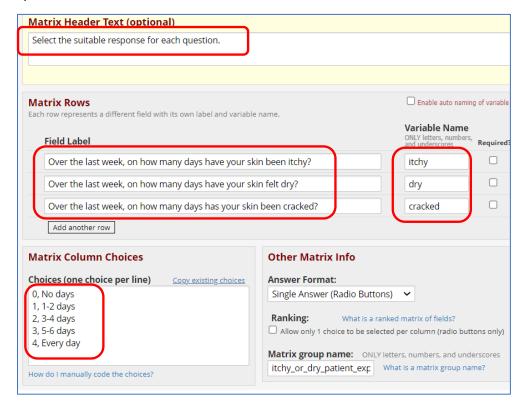


9) When the participants open the survey, they can choose their preferred langue.



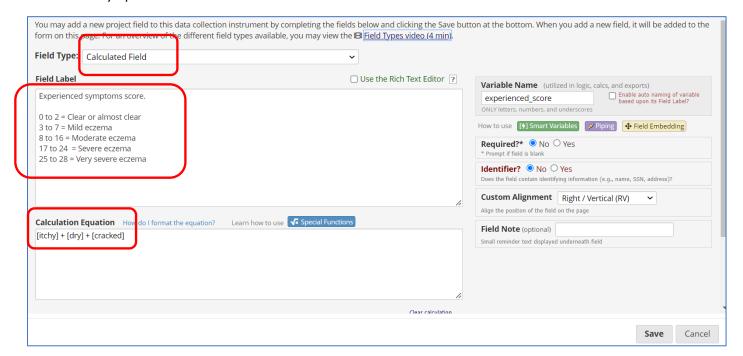
extra: Matrix (e.g. for Likert Scale)

- 1) Go to Designer
- 2) Click Create a New Instrument from scratch, called "Symptoms Experience by the Patient"
- 3) Click Add Matrix of Fields



extra: Calculated Fields

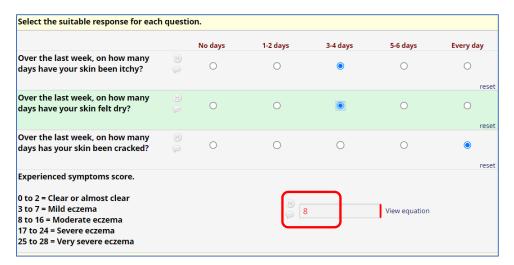
To calculate symptoms score



Designate events for collecting "Symptoms Experience by the Patient" data.

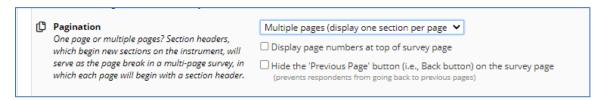
Data Collection Instrument	Event 1	Month 1 visit	Month 2 visit	Final survey
Baseline Data	~			
Symptoms Severity Score	~	✓	/	
Adverse Effects		4	4	
Symptoms Experience by the Patient	4	4	4	
Research Participant Perception Survey - UP (survey)				~

Go to Add/edit records and test how the calculated fields works.



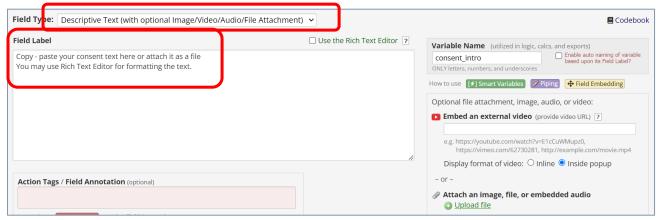
extra: Pagination (in Surveys)

Go to "Research Participant Perception Survey" => Survey settings and select Pagination => Multiple pages (display on section per page)



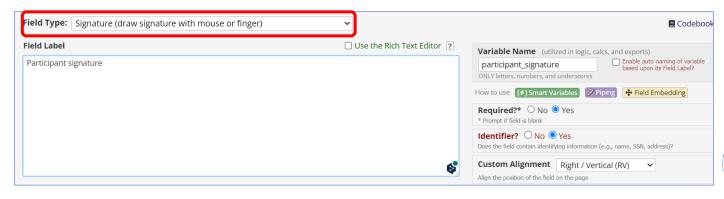
extra: Consent

- 1. Create a new instrument called "Consent"
- **2.** Copy your consent text into the new instrument.

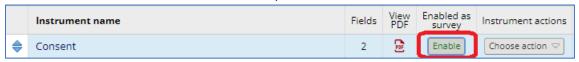


Further information about the consent, see e.g. Flamma: https://flamma.helsinki.fi/en/group/tutkimuksen-tutki/tutkimuksen-tietosuoja-asiat (e.g. Privacy Notice for Research) or FSD's guide-on-informing research-participants

3. Add the signature under the consent statement and a date validated field.



4. Enable the consent instrument as a survey.



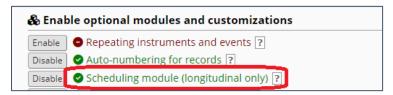
5. Within survey settings, scroll down to eConsent framework. Enable the auto-archiver + eConsent Framework.



- **6.** Finish up by clicking the Save Changes button.
- Test the entire eConsent workflow to ensure everything is working as expected.

extra: Scheduling module

For generating schedules for calendar, based on the events in the "Define My Events" tab.

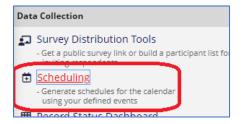


"Define My Events" table will look like this:

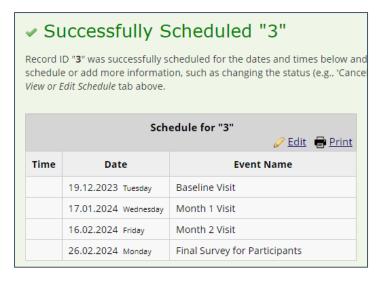


- 1. Days Offset: The number of days since the start of the study this event is scheduled to occur.
- 2. Offset Range, Min/Max: Allows for scheduling within an assigned range of days.

To generate a schedule for an individual record, select the "Scheduling" tool under "Data Collection" on the left-hand panel.







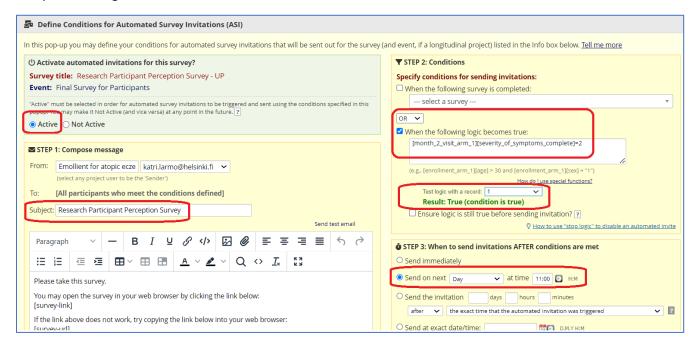
Note: The scheduling module does not integrate with automatic survey invitations or alerts. Its intended use is for study staff to stay organized and generate participant schedules.

extra: Automated Survey Invitations

Online Designer => Automated Invitations => Set up



Compose message and define the conditions when the invitation is sent



Acknowledgements:

These exercises are much inspired by

- the Center for Clinical and Translational Science, University of Illinois Chicago RedCap Practice Workshop
- RedCap education of biostatistician Eliisa Löyttyniemi, University of Turku
- The University of Florida Clinical and Translational Science Institute (CTSI) RedCap education
- UofA REDCap Support What are Arms?. [25.2.2022]
- How to set up eConsent in REDCap by Vanderbilt Institute for Clinical and Translational Research
- Longitudinal data collection in REDCap by Illoinois IHSI Interdisciplinary Health Sciences Institute
- <u>Automatic Survey Invitations (ASI)</u> by University of Wisconsin-Madison School of Medicine and Public Health
- <u>Data Structure with REDCap: Active Design Rather Than Passive</u> by Ali Chambers, Advance Clinical and Translational Research, Brown University
 - see e.g. 7:49 min: Repeated events wide format data structure vs. long format data structure (numerous rows per person)
- Ideas for the symptom score and experienced symptoms score taken from: EASI score and POEM

