RBDCOV Project

Target communication tools

Deliverable 9.2

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Target communication tools

Work Package 9: Community Engagement

Deliverable 9.2

Change log

Version	Author	Description of Change
V0.1	EATG	Preliminary draft prepared by WP9 lead
V0.2	Zabala	Review of draft by Coordinator
V1.0	EATG	Final draft ready for submission

Table of Contents

Table of figures

1. INTRODUCTION

The report on the participants' centric design protocol for RBDCOV provides a description of the main points that have been considered and discussed during the preparation of the project trial protocols, accompanying documents and information materials related to the clinical trials. The focus has been on providing input toward the WP4 'New emerging variant vaccine clinical trial phase III with the adult population in the participating countries with pre-existing immunosuppressive conditions' protocol. The preparations for community involvement in WP3 is ongoing due to changes to the WP3 trial protocol.

Reference to community in this context, means mainly the community of people living with or affected by HIV, although efforts are ongoing to ensure people representing the other immunocompromising conditions, and adolescents/children are included in giving input.

This document outlines the **Target Communication Tools** that have been developed and are planned throughout the project in order to communicate complex scientific and medical information into layman's language. The focus when contributing to tools and materials has been on providing input toward the WP4 'New emerging variant vaccine clinical trial phase III with the adult population with pre-existing immunosuppressive conditions' protocol, as well as to WP8 Dissemination and Communication, which outlines the channels and activities to communicate about the project, its progress and outcomes. Any materials developed to communicate to participants in the trials, the community or to the public in general via the different established project channels call for specific input from EATG and hence the Community Advisory Panel to ensure that the community perspective is represented. The project consortium, and especially the partners in WP8 also work toward ensuring that the information materials developed to communicate the project's results and their implications to the public are accessible and appropriate. EATG and the CAP play a key role in this process of developing and reviewing materials before they are published.

EATG have extensive experience in ensuring that the perspective of community (people living with HIV, patients or participants in trials, for example) is incorporated in all phases of the R&D process. Since 1992, the European Community Advisory Board has been working with different stakeholders for this purpose. The formation of the Community Advisory Panel (CAP) in RBDCOV follows a similar approach, with expert community members being actively engaged in the design and development of the clinical trials, recruitment and implementation processes.

2. ACRONYMS AND ABBREVIATIONS

EATG – European AIDS Treatment Group
CAP – Community Advisory Panel

3. EXPLANATION OF THE DELIVERABLE

This deliverable is associated with ***Task 9.2 Patient information and documents*** which is carried out throughout the whole project and is led by HIPRA with collaboration from EATG as work package lead. From M2-M6 of the project, work in WP9 focused on the design and revision of several documents as part of the delivery of the clinical trials, such as the trial protocol, informed consent form, participant diary, and other related participant information annexes addressed to participants. These are usually written in a technical/clinical language that is not always easy to understand by the general population. There are also considerations to be made around real-life experiences in participating in a clinical trial from the participant perspective. Involvement of participants or patient or community experts and their feedback in the drafting and design process of these documents strengthens the ethical approach and helps to anticipate possible issues and concerns that may arise during the trial. Throughout, EATG through the CAP has ensured that the information delivered to participants involved in the clinical trial and the wider public is accessible, complete, transparent, reader-friendly and comprehensible with regards to the objective of the project, the involvement of members of the community.

Additionally, as part of the engagement activities foreseen in the project, additional materials are being developed and planned (such as infographics, videos, webinars, etc.). These tools are meant to provide not only relevant and up to date information about the project, but they will also help to monitor the expectations and concerns of the participants regarding the development of the vaccine. This task is being developed in close collaboration with ZABALA through WP8, where they will create visuals such as videos and infographics, and create communication messages in consultation with EATG, the CAP and HIPRA.

Translations
Translation of trial and project information into the languages of the countries of the trial sites has been identified by EATG and the CAP as necessary to the community and general public. For this reason, EATG will ensure that necessary materials will be translated by the community to maintain the accessible language and appropriateness in the CAP-reviewed English versions of materials.

Infographic

An example of a CAP-reviewed material is the initial design of an infographic developed by HIPRA and Zabala to explain how the vaccine works that is being developed in the framework of the project (see Figure 1). The infographic shows a comparison between a recombinant protein vaccine (the type of vaccine used in the RBDCOV project) and a vectored vaccine (used in other vaccine development processes).

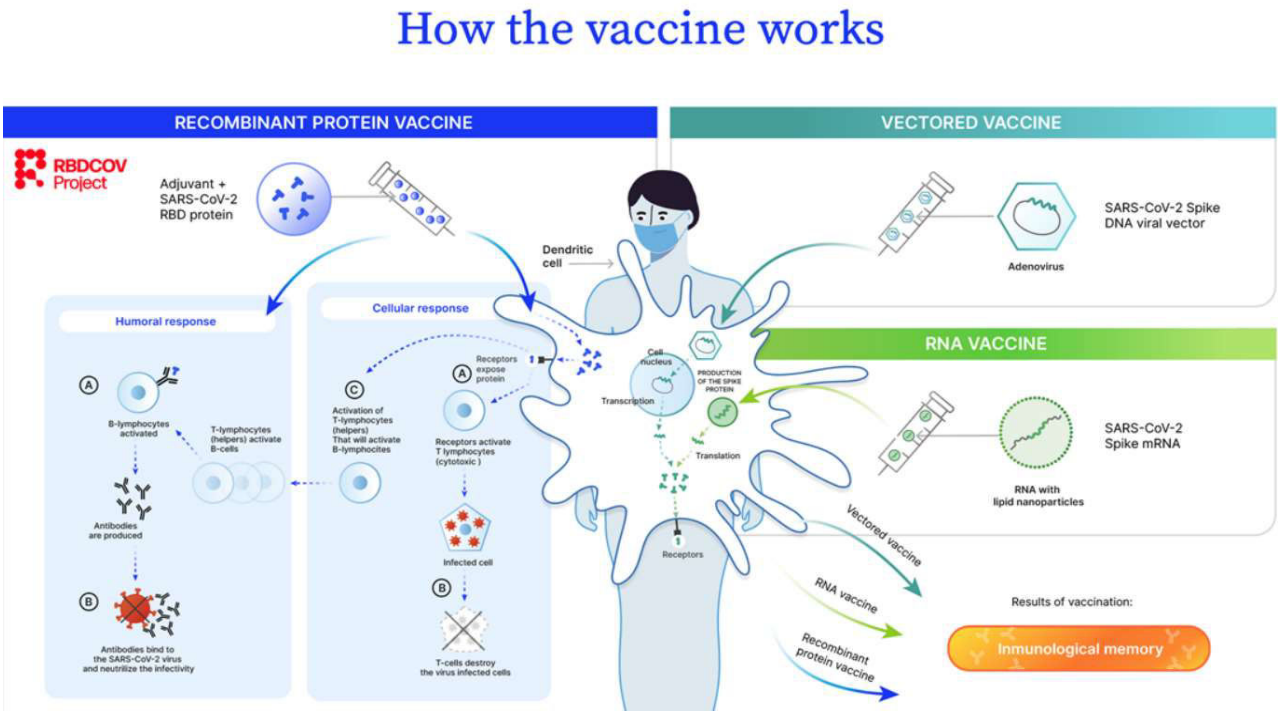

Figure 1: Infographic – How the vaccine works

The image was shared with the EATG team and CAP for their review in the months of April and May 2022. As with other review processes, the CAP provided extensive feedback on the infographic related to the graphic design, clarity of concepts and information presented, use of technical terminology, etc. Refer to *Annex 1* for a summary of all comments provided by the EATG team and CAP members. This input was shared and discussed in detail with Zabala. It was decided that the infographic would need to be redesigned and that additional visual material would need to be created that would be better suited for different target audiences - scientific/ medical/ research community, trial participants, people with immunosuppressive conditions who may be following updates and the general public. EATG and the CAP will co-design and review the new versions of the infographic.

Project Website: FAQ and Glossary for Participants

EATG is a partner in WP8 on Communications and Dissemination and is collaborating closely with Zabala on the development of communications materials and dissemination efforts throughout the project, which closely overlaps with activities related to the development of targeted communication tools.

Currently, the main focus of the CAP has been on improving and expanding the list of questions and answers for participants currently available on the RBDCOV website (direct link below).

https://rbdcov.eu/faqs-for-participants/

In this capacity, in M3 (April 2022) of the project, following the launch of the project website, the CAP was involved in reviewing its sections to ensure that the information presented was clear and easy to find, to read and understand from a community perspective. The CAP focused specifically on the section on the FAQs for participants and identified this as a section that needed to be expanded with additional information that was more specific to the trial of the project and relevant to potential participants. For the time being, the FAQ focuses on the adult trials under WP4 and does not cover information related to WP3 on trials with children and adolescents. Information about WP4 trials was published on the Clinical Trails database website: www.clinicaltrials.gov, which the CAP reviewed.

Annex 2 provides a summary of the feedback the CAP provided upon reviewing the RBDCOV website including the following:

- technical aspects of the site (navigability, design);
- use of technical terminology and clarity;
- content of the FAQs

The CAP formed a working group to review the original FAQs and come up with additional questions and answers and they are working on finalising an initial draft of the section to share with the rest of the consortium for their review. Refer to *Annex 3* for the draft Q&A section which has been compiled and colour-coded. The file includes sections marked in different colours and specifies the status of each question: in green (complete question), yellow (uncertain, needs work), and red (incomplete, requires input), along with columns of feedback from CAP members and the EATG team.

The CAP also suggested that a Project Glossary may be a useful addition to the website, which would provide easily accessible, clear explanations of medical or scientific terminology used in all sections of the website. The members agreed that the FAQ section is a priority as it is currently visible on the site and that working on new questions and answers will aid in identifying potential terms that could be included in a glossary. Annex 4 provides a summary of potential terms that may require detailed definitions. The CAP also referred to other community resources and tools to determine what terms should be included such as:

- HIV Cure Glossary
  https://www.avac.org/resource/hivaids-cure-glossary
- EU Patient Engagement Through Education
  https://toolbox.eupati.eu/glossary/
- WHO Clinical Trials
  https://www.who.int/health-topics/clinical-trials#tab=tab_1

Once the FAQ section is complete, content for this particular section will be translated into Spanish, Catalan and Turkish in line with the languages of the participant countries taking part in the clinical trials of the project.

WP3: Protocol

Similar to the involvement of the CAP in the review of the WP4 protocol, once clarifications have been made by WP3, the CAP will provide feedback from the community perspective of the trial protocol, participant diary, informed consent and any additional participant information sheets in all 3 languages. EATG anticipate that there will also be the need to review a recruitment form or recruitment process. As per WP4, the CAP will review the publicly available information on the trial on the Clinical Trails database website: www.clinicaltrials.gov

Other communications

EATG anticipates that there will be a range of further communication materials such as updates to the website, social media postings, infographics surrounding the project, as interim results are released. EATG will ensure that the EATG team and the CAP will be meaningfully involved in the development of these materials, and, where deemed necessary, in the translation of the materials.

Community webinar

Specifically, EATG will host a community-focused webinar on the project trial results, where trial participants, the community of people living with HIV and other patient communities will be invited, via EATG networks. The trial and project results will be presented in an accessible way with space for any questions.

Abstracts/ presentations

EATG have also suggested to the Consortium that interim project results and final project results be disseminated via European and international conferences, particularly HIV conferences. Having community input on the development of submitted abstracts, presentations and potential articles will ensure they are accessible.

Possible conferences identified are:

- EPF Congress
- International AIDS Society (IAS) conferences
- HIV Drug Therapy (Glasgow)
- European AIDS Conference (EACS)
- Conference on Retroviruses and Opportunitistic Infections (CROI)

4. ANNEXES

Annex 1 - Comments on Infographic "How Recombinant Protein Vaccines Work" by EATG Review Team.
Annex 2 – CAP review on RBDCOV website and FAQ section
Annex 3 – RBDCOV participant Q&A sheet
Annex 4 – RBDCOV suggested terms for website Glossary

RBDCOV Project

Comments on Info-Graphic "How Recombinant Protein Vaccines Work" by EATG Review Team

General comments:

- not clear who the target group is for the infographic and what exactly it is meant to convey?
- If infographic is meant also for general public, it is too technical and complex, not accessible in terms of terminology used and also size of font, hard to see.
- If the focus is the recombinant vaccine, then maybe change the colour scheme to highlight it. Also maybe reduce info about the other two types of vaccines, or move it away somehow.
- Heavy use of text
- It's not clear where to start looking at the diagram.
- It's good that the person figure used is neutral and doesn't look like anyone in particular.
- It would be helpful to briefly describe the virus first (as the CDC did, cf. picture at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html
- It would also be helpful to briefly describe the three different types of vaccines (as the CDC did, cf. picture at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html (see one example in the table at the end of this document).
- There is no mention that the product of both the mRNA- and Vector-based vaccine is also a protein. The protein symbols should be labeled as such. The term "antigen" could also be introduced.
- „humoral response" and „cellular response" should be briefly explained (i.e. „antibodies and other molecules that can fight pathogens" and „immune cells that can recognize and kill pathogens and infected cells") .
- The huge „dendritic cell" is visually distracting with its many lobes. It also looks like a splatter/ explosion which is very off putting and violent for a graphic about a vaccine. Change to something more spiky/ not reminiscent of human fluid/ splatter.
  It is also white - the colour of a human fluid- this should be something more neutral e.g. light grey or light blue. And it is nowhere explained, where these dendritic cells reside.
- The graphic shows the content of the adenovirus entering the nucleus. This might promote fear that it could change the genetic material of the cell.
- The creation of a new separate infographic that is more tailored to the community and general public would be a very good idea, as they may not have scientific knowledge to understand specific terms, words and vaccination process in general.
- A different design (simpler to understand) should be introduced and minimize number of words that have specific meaning and are understandable only for medical staff.
- A simpler wording of the infographic could give the same amount of information, but simultaneously technically it would be possible to provide more information per topic

if clicking each title (RNA vaccine, Vector Vaccine, humoral immunity and so on). So, you could go from the simple „surface" graphic into a more technical „in-depth" explanation (as provided below, or it can be reworded even simpler)
- Ideally, this kind of texts can be opened while clicking each topic to avoid overloading the infographic.
- It is not explained what the difference / advantage of the protein vaccine is.
- The **colours** used don't highlight that this project is using the RBDCOV vaccine, so doesn't show the difference well between them and the one we should focus on.
- The eye is not drawn to the **immunological memory box**, which we assume is the main point of the infographic to show that ultimately the 3 types of vaccine lead to the same outcome due to the position in the bottom corner.
- Font is too small and is not the same style throughout. Suggest to align the font so it is the same style.

In the box „**cellular response"** it looks like the two events „receptor activates T-Lymphocytes" and „infected cells" / „T-cells destroy the virus infected cells" occur immediately after one another. However, this is not the case. So, it would be easier to understand if the arrow would be replaced by another symbol (broken arrow like --/ /-→) or an additional explanation added („once an infection occurs…")

As it is now, the labelling with A, B, C doesn't make too much sense. What do you want to say with it?

Possible explanations of the scientific terms:

RNA Vaccine	RNA Vaccine – a) Ribonucleic Acid, a nucleic acid present in all living cells, in some viruses. Its principal role is to act as a messenger carrying genetic information. b) Most vaccines contain weakened or dead bacteria or viruses, however, scientists have developed a new type of vaccine that uses a molecule called messenger RNA (mRNA) rather than part of actual bacteria or viruses. Messenger RNA is a type of RNA that is necessary for protein production. Cells use the information in genes to create a blueprint for making proteins – this is the mRNA. Once cells finish making a protein, they quickly break down the mRNA. mRNA from vaccines does not enter the nucleus and does not alter the DNA.
Vector vaccine	In this type of vaccine, a small piece of the genetic material from one virus is placed in a modified version of a different virus (viral vector). When the viral vector gets into your cells, it delivers genetic material from the virus that gives your cells instructions to make copies of the S protein. Based on it, your immune system responds by creating antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies and defensive cells will fight the virus. Viral vector vaccines can't cause you to become infected with the COVID-19 virus or the viral vector virus. Also, the viral vectors cannot multiply.
Protein vaccine	Protein vaccines include only the parts of a virus that best stimulate your immune system. This type of COVID-19 vaccine contains harmless S proteins. Once your immune system recognizes the S proteins, it creates antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies will fight the virus.
Humoral Response	Antibodies and other defensive molecules are part of the "humoral response" (because they are dissolved in the blood liquid)
Cellular Immunity	All the defensive cells that help to clear an infection are called "cellular immunity"
Immunologic memory	Immunologic means, that the immune system can remember the antigens that previously activated it and launch a quicker and more intense immune reaction when encountering the same antigen a second time

Where available

RBDCOV Project

COMMENTS FROM : COMMENTS FROM: RBDCOV Community Advisory Panel (CAP)

TITLE OF DOCUMENT : RBDCOV project website – FAQ for participants section

GENERAL COMMENTS

- This Q&A page lacks relevant questions and answers; it is often too vague or even confusing and inconsistent.
- Some questions deserve more concrete answer. Sometimes, specific formulation is conflated with general formulation. I.e., description of the two CTs.
- Similar to other places (protocol & PCF), Turkish part seems to be a bit neglected. While most research work is done in Spain, by Spanish researchers and funded by a Spanish company, any participant country deserve the right attention. For instance, we'd expect to see information on personal data outside of EU, specific to participant countries.
- The pages are not very participant-friendly (vocab, acronyms, lack of explanations, etc.) but improving them in that direction should not take too much effort.
- Glossary should be created and linked to every term that might read difficult to participants.
- Any reference of "subject" must be changed to "individual" or "participant"

SPECIFIC COMMENTS

Line no[1]. + paragraph no.	Original text	Comment and proposed change (if applicable)	Type of comment (e.g. major objection, for clarification, ..)	WP8 Comments (accept or reject)
Tech aspects of the page		1. Every click on a question (to open or close the answer box) will scroll the page down automatically which is…. disturbing. This is happening on both, Windows PC (using Chrome and Edge) and Android phone (Chrome). On the phone is worse, the space is limited.		

[1] Where available

		2. On PC, it's enough to hover the mouse over the menu to see what options are there. On the phone, that menu behaves quite differently a) Clicking on the arrow may or may not take you to a new page. This happen even if no option from submenu was selected. This is not consistent (it's not happening all the time). When retracting the menu, it will almost always, take me to the main page of the main option button in the menu. Ex. 'About RBDCOV'.		
Title	The European RBDCOV project will study HIPRA's COVID-19 vaccine in children, adolescents and immunocompromised patients	Add explanation of the meaning of "immunocompromised"	**Suggestion**	
Title	RBDCOV is a European project that will perform two clinical trials currently based on previous AEMPS and EMA's advisory meetings.	**RBDCOV is a European project that will perform two clinical trials currently based on previous AEMPS (**Spanish Agency of Medicines and Medical Products) **and EMA (European Medicines Agency)'s advisory meetings**	Major comment: avoid acronyms as much as possible	
Page 1	Towards a new COVID-19 vaccine for children, adolescents and immunocompromised patients using a recombinant protein RBDCOV will test the efficacy, tolerability, and safety of the vaccine against the variants of COVID19	Replace "**patients"** by **people**. Add a glossary to the website and for each word such as "recombinant" a link to the definition.	Major suggestion	

Q&A, first page Introduction (I suppose?)	See Image 1	This part seems to be suspended in the air, with no complete purpose and, at best, a sudden start. I would start with What is RBDCOV Project. What the initials stand for, what is the project about (mission).	Suggestion	
General information about clinical trials: **What are randomised trials?**	Randomisation ensures that at the beginning of the study the **intervention and control group** are comparable and that the selection to receive treatment is not biased.	While I support your response, this response rather answers to 'why randomisation is necessary'. I would suggest adding, at the beginning, what randomisation is. My suggested answer: 'A trial can have two or more groups of participants, in order to compare the results produced by each group. After we recruit the number of participants we aimed for, and before the start of the study, we assigned them randomly to one of the trial's groups. This is to ensure… [your answer].' What means intervention group? It's worth an explanation. I provided another suggestion to the right. →→	Suggestion for an answer to this question: 'A randomised trial consist in two or more trial groups, within the same study, in order to compare the results between them. Most clinical trials [or our clinical trial] include at least an intervention group (the group to which the study vaccine is administered) and a control group (to which a placebo – a product with no effects). Once we have the number of participants needed to run the study, we distribute them randomly to one or another group. This is important to ensure that the	

			results between the groups are comparable and are not biased'.	
What is inclusion criteria	What is inclusion criteria	What are inclusion criteria	change	
What is exclusion criteria	What is exclusion criteria	What are exclusion criteria	change	
What is exclusion criteria	Exclusion criteria are a set of predefined definitions that is used to identify subjects who will not be included or who will have to withdraw from a research study after being included.	Exclusion criteria are a set of predefined definitions that are used to identify subjects who will not be included or who will have to withdraw from a research study after being included.	change	
What is inclusion criteria?	Inclusion criteria are a set of predefined characteristics used to identify subjects who will be included in a research study.	Not subjects, participants	Recommendation	
What is exclusion criteria?	Exclusion criteria are a set of predefined definitions that is used to identify subjects who will not be included or who will have to withdraw from a research study after being included.	Not subjects, participants	Recommendation	
What is exclusion criteria?	Exclusion criteria are a set of predefined definitions that is used to identify subjects who will not be included or who will have to withdraw from a research study after being included.	1/Replace paragraph as follows: Exclusion criteria are a set of characteristics used to identify persons who will not be included in the research study, or will have to withdraw from it after being included.	Major objection as above (subjects)	
What is RBDCOV?	RBDCOV is a project that aims to test the efficacy, tolerability and safety of the HIPRA's vaccine against the different variants of COVID-19. The	…is a clinical trial that tests how efficient, tolerable, in terms of side-effects, and safe, the HIPRA…	**Major suggestions**	

	Covid-19 vaccine being developed by HIPRA is an adjuvanted recombinant protein vaccine, based on a receptor binding domain (RBD) fusion heterodimer containing variants B.1.1.7 (alpha) and B.1.351 (beta) of SARS-CoV-2. The initiative is an innovative vaccine-focused research project that brings together the expertise of a number of European groups and companies in rational design of animal and human vaccine immunogens, vaccine manufacturing, distribution and commercialisation, cellular and humoral immune responses, clinical trials, regulatory issues, stakeholders involvement and patients perspective. COVID-19 is a respiratory disease categorized by the WHO as a pandemic that has provoked obviously a health crisis, but a socio-economic crisis too because of the measured needed and adopted by the different countries to try to contain the spread of the virus.	Needs rephrasing here or at least a glossary. Why not insert a video that would explain all of it? This sentence is too long sentence, with no breaks and uses complicated terminology. As we all know, …. Perhaps start with this paragraph on the page?		

What is RBDCOV?	RBDCOV is a project that aims to test the efficacy, tolerability and safety of the HIPRA's vaccine against the different variants of COVID-19. The Covid-19 vaccine being developed by HIPRA is an adjuvanted recombinant protein vaccine, based on a receptor binding domain (RBD) fusion heterodimer containing variants B.1.1.7 (alpha) and B.1.351 (beta) of SARS-CoV-2.	Does it mean for patient that this vaccine cannot be effective for Delta type of COVID? Patient can consider that this trial can be irrelevant to today's situation. I think it will be better either not to mention Alpha and Beta types OR to provide more clarity about future benefits	Clarification	

What BDCOV will do	The purpose behind RBDCOV project is to **offer a new tool to control the pandemic** at short-medium and long term, and to **manufacture and test the first recombinant protein-based vaccine** to be authorised in Europe. RBDCOV is going to generate robust data to demonstrate the **safety and immunogenicity of this vaccine given as a booster vaccination** to induce higher and more durable immune response, specially towards new and future viral variants, which will be bridged for the effectiveness in the prevention of COVID-19. The proposed strategy benefits from the partners experience in different fields and will permit to address the following issues that should permit a significant advancement: • Flexible platform ready to generate antigens of any future variants. • Inclusion of children and immunocompromised adults. • Booster for future vaccine campaigns. • Other challenges associated with COVID vaccination. • Understand the importance and limits of developing new	**a new tool (vaccine)** Again, a glossary would help readers. RBDCOV is going to: this is research, we don't know the answer, please replace by: RBDCOV "may generate" or "might generate" Immunogenicity: add glossary. Especially (spelling) Which will be bridged: what does this mean to a lay reader? Partners' (spelling) – will allow to – that should allow for	Major comments	

	vaccines in a pandemic situation.			
The clinical trial RBDCOV contribution	The purpose behind RBDCOV project is to offer a new tool to control the pandemic at short-medium and long term.	The purpose behind the RBDCOV project is to offer a new tool (vaccine) to control the pandemic at short-medium and long term		
Phase I	The purpose of Phase I is to ensure that the treatment is safe in humans and to determine how and where it distributes within the body.	Within the human body.		
Phase II	The purpose of a Phase II Clinical Trial is to determine the right dosage and effectiveness in treating that particular disease.	The purpose of a Phase II Clinical Trial is to determine the right dosage and effectiveness of a medicine in treating a particular disease.	Suggestion for better readability	
Phase IV	The safety and effectiveness of the new medicine is evaluated in larger numbers of patients and compared and combined with other available treatments.	The longer-term safety and effectiveness of the new medicine is evaluated in larger numbers of patients and compared and combined with other available treatments.	Suggestion for better readability	
Clinical trial 1	A clinical trial study phase I/II involving healthy children and adolescents aged >2 years and >12-18 years to demonstrate the effectiveness of the RBD protein vaccine against SARS-CoV-2 in paediatric population.	…in the paediatric population		
Clinical trial 2	This clinical trial will help to achieve the RBDCOV aim, which is to develop a safe and effective vaccine for the prevention of COVID-19 given as a booster vaccination to induce a higher and more durable immune	especially		

	response, specially towards new and future variants.			
What is a clinical trial	Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioural intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device is safe and effective in people.	Suggestion to replace by: Clinical trials are research studies performed in humans. They aim to evaluate a medical, surgical, or behavioural intervention. They are the primary way by which researchers find out if a new treatment, like a new drug or diet or medical device is safe and effective in human beings.		
What is a clinical trial?	They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device is safe and effective in people.	It is better to mention here **"**prev**e**ntive vaccines" as well.	Reccomandation	
https://rbdcov.eu/faqs-for-participants/ What is a clinical trial?	Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioural intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device is safe and effective in people.	**Suggestion to instead use the definitions from WHO:** (From WHO web site); https://www.who.int/health-topics/clinical-trials#tab=tab_1 Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care. Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children. OR EUPATI https://toolbox.eupati.eu/glossary/clinical-trial/	Recommendation	
What are the phases of a clinical trial?		**https://toolbox.eupati.eu/glossary/phase-i-trials/** https://toolbox.eupati.eu/glossary/phase-ii-trials/ https://toolbox.eupati.eu/glossary/phase-iii-trials/	Recommendation	

		https://toolbox.eupati.eu/glossary/phase-iv-trials/ A visual like this would be very helpful https://toolbox.eupati.eu/wp-content/webp-express/webp-images/doc-root/wp-content/uploads/sites/4/2020/07/phases-clinical-development-v1_EN-scaled.jpg.webp I find the explanations of Eupati easier to understand One sentence may not be fully explanatory to someone who is not well-versed in the subject.	I find the explanations of Eupati easier to understand One sentence may not be fully explanatory to someone who is not well-versed in the subject.	
Introduction (I suppose?)	**Clinical trial 1** **A clinical trial** study phase I/II involving healthy children and adolescents **aged >2 years and >12-18** years to demonstrate the effectiveness of the RBD protein vaccine against SARS-CoV-2 in paediatric population. **Clinical trial 2** This clinical trial will help to achieve the RBDCOV aim, which is **to develop a safe and effective vaccine for the prevention of COVID-19 given as a booster** vaccination to induce a higher and more durable immune response, specially towards new and future variants.	• Maybe 'This is a phase I/II clinical trial, involving children…'? • **Phase I/II**: Although you later talk about what a phase trial is, maybe it's a good idea to say what a phase I/II is? Or why it is I/II and not I or II? • **Age**: I suppose it is meant to show that the phase study is for two groups of people: 2 – 11 years old and 12-18 years old. I think this formulation is cleaner. • **Clinical trial 2:** this sounds rather like the overarching mission of RBDCOV Project, as I understood it, rather a quasi-specific objective or aim of this specific trial. In addition, there is no reference to what phase we are talking about in this trial. Additionally, is this trial limited to children and adolescents? • While the first CT gives a hint of specificity, the second one lacks this totally. • Suggestion: I would remove this part completely, and introduce some sort of information box, including in it information about what is RBDCOV Project about, its mission and, if you'd like, a broad picture of the trial. For instance, you could mention how many trials are involved, and what you want from them, in a layman language (for instance, 'in X trial we are		

		testing how safe and efficient our vaccine is, is another', etc.). This way, the participant will have a broad picture of the context and its place in the context.		
What are the phases of a clinical trial?		Usually Phase 1 is safety, Phase 2 is dose finding, Phase 3 is efficacy in a larger cohort and Phase 4 is post marketing /additional indication	adapt	
Clinical trial phases	Clinical trial phases	It would be great if there is a grand scheme/diagram in the page where the participants can see where they are in the research.	Suggestion (similar, perhaps, with the last point made previously)	
General information about clinical trials: **What are the phases of a clinical trial**?	A Phase IV trial: for drugs or devices takes place after the regulatory agency approves their use. A **device or drug's effectiveness and safety** are monitored in large, diverse populations.	Overall, I appreciate the whole answer to this question. I would only clarify it a bit. Suggestion to add: *'… device or drugs long term effectiveness and safety…'*	Suggestion	
Where will the trial take place?	The clinical trials will be conducted in two countries: Spain and Turkey. In the case of Turkey, they will be conducted solely at Metpharm's facilities, but in Spain, they will be divided between several centres: Vall d'Hebron Research Institute (VHIR) (Barcelona), Hospital Clínic de Barcelona (Barcelona), Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta (IDIBGI) (Girona), Fight AIDS and Infectious Diseases Foundation (FLS) (Badalona).	1/Replace subtitle by: Where will the trials take place? 2/while in Spain…		
When will the clinical trials take place?	The recruitment will start on March 1, 2022 and will end on Jun 30, 2022.	1/I suggest to change subtitle into: When will participants in the trials be recruited? – because the trial will take longer to take place. 2/Replace phrase by: The recruitment of participants into the clinical trials started on March 1st, 2022, and will end on June 30th, 2022.		

		3/Are the dates here actually correct?		
How often do I have to visit the hospital?	Depending on the clinical trial in which you are participating, visits to the hospital for monitoring visits vary. If you need more information, please contact us via the contact form at the bottom of the website.	1/ The second word "visit" can be suppressed: …change to: "visits to the hospital for monitoring vary." 2/ If you need more information, please contact us via the contact form at the bottom of the website. This is not very participant-friendly. A phone number or email, directly in this paragraph would be nice.	Major suggestions	
What it means to take part in RBDCOV clinical trials? **How often do I have to visit the hospital?**	Depending on **the clinical trial in which you are participating**, visits to the hospital for monitoring visits vary. If you need more information, please contact us via the contact form at the bottom of the website.	This sounds quite confusing. Do you talk about one of the two clinical trials described at beginning of the web page or are there more than that? If this Q&A web page is regarding those two trials, I don't see why not including the number of visits and brief purpose of those visits?	Clarification and suggestion	
How are my own data protected?	The EU General Data Protection Regulation – GDPR – aims to standardise and strengthen the protection of personal data across the EU and for other country's data being "processed" within the EU, since May 2018. The GDPR also applies for Clinical trials. If the person confirms its participation in a trial, data can be only processed for the purpose of that trial. The EU GDPR requires that personal data is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.	If you confirm your participation in a clinical trial, data can be only processed for the purpose of that trial. The EU GDPR requires that personal data is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes. An individual has the right to withdraw their consent at any time during the conduct of the clinical trial, without necessarily having to provide any explanation for this. This information should be given to people before they consent to participate in a clinical trial. (Note: I don't see the link between data protection and this section). The first section on GDPR refers to data from non-EU countries processed in the EU. Does the EU regulation on data protection apply to Turkey? If not,	Major suggestions.	

	An individual has the right to withdraw his/her consent at any time during the conduct of the clinical trial. This information should be given to the patients prior to giving their consent to participate in the clinical trial.	then, perhaps, it's worth mentioning about local regulation? Since in this Q&A page is mentioned that Turkey and Spain are parts of this project, I would suggest to not limit to add 'local regulation' but something more specific, where Turkish participants can go to inform themselves.		
How are my own data protected?	If the person confirms its participation in a trial, data can be only processed for the purpose of that trial. The EU GDPR requires that personal data is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes. An individual has the right to withdraw his/her consent at any time during the conduct of the clinical trial. This information should be given to the patients prior to giving their consent to participate in the clinical trial.	Here should be mentioned about confidentiality issues as well. The patient should be aware that all predictable measures will be kept to ensure confidentiality of study participant. And to add special article that envisages consequences of violation of confidentiality (that is relevant to each country, where clinical trial is taking place).	Suggestion	
Which population groups can participate?	The study will be conducted in **healthy children and adolescents** and includes an expansion cohort with individuals with immune-related conditions.	**Children:** clarify that there are two separate trials: one in children and adolescents and one in individuals with conditions that suppress the immune system	Clarification and suggestion	
Which population groups can participate?	The study will be conducted in healthy children and adolescents and includes an expansion cohort with individuals with immune-related	Meaning of the second phrase is not understandable. Term gender-disaggregated needs clarified.		

	conditions. Furthermore, the study has been designed all data to be sex and gender-disaggregated and consider critical social factors intersecting with sex/gender, such as age, social origin, ethnicity/migration, and disability.	**Gender-disaggregated:** I am trying to figure out how this answers the question? In the layman language I think this means that 'all data to consider sex and gender as separate data point and compare them against critical social factors…'? If this is the case, I would suggest rephrasing. Does that also mean that only cisgender individuals are eligible for participation? **Has been designed:** or 'has designed'? Or 'has been designed so that all data be…'?		
What it means to take part in RBDCOV clinical trials? **Where will the trial take place?**	The clinical trials will be conducted in two countries: Spain and Turkey. In the case of Turkey, they will be conducted solely at Metpharm's facilities, but in Spain, they will be divided between several centres: Vall d'Hebron Research Institute (VHIR) (Barcelona), Hospital Clínic de Barcelona (Barcelona), Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta (IDIBGI) (Girona), **Fight AIDS and Infectious Diseases Foundation (FLS) (Badalona).**	This information appeared only partially in the full protocol. Only one Spanish Centre (in bold) and none of Turkish centres is mentioned there. In the protocol is specified that there will be 6 centres involved. Combining information from the protocol and from this website it makes more sense. Extract from the protocol: *T-cell mediated response analysis will be conducted at the IDIBAPS of Hospital Clínic of Barcelona, Spain, and at IrsiCaixa AIDS Research Institute, at Hospital Germans Trias i Pujol, Badalona, Barcelona, Spain*. If this is independent to the protocol we view, then disregard this one. Else, keeping the process clean and consistent across the projects/departments is crucial.	Suggestion	

How often do I have to visit the hospital?	….. please contact us via the contact form at the bottom of the website.	No contact form available at bottom of website	**clarification**

What it means to take part in RBDCOV clinical trials?		Will more questions be added to this section? **For example;** **Why should I participate?** **What is a healthy volunteer?** **What is a protocol?** **What are eligibility criteria?** **What is the placebo effect?** **What is the difference between single-blind and double-blind studies?** **Are there risks involved in participating in a clinical trial?** **What safeguards are there to protect participants in clinical research?** **Can I stop participating at any time?** **Will I be compensated for participating in a clinical trial?** **Will my insurance need to cover any visits?** **If I am interested in a specific clinical trial, how can I learn more?** **Is it possible to experience side effects during a clinical trial?** **What are the advantages of being a participant in a clinical trial?** **How long can a clinical trial last?** **If the treatment appears to be helping a patient during a clinical study, can they continue taking the medicine after the trial has finished?** **Other questions:** 1. What are potential risks associated with your participation in the trial? 2. What, precisely will I be doing in this study? The word 'vaccine' barely appears on the page (only in the introduction to the two CT and in no answer to any question). 3. Will the participation be for free?	**clarification**

		4. How much time will I spend in the clinic/hospital/centre? 5. What will happen during the visits? 6. If blood sample is taken, why? What if I start having side effects hours or days from the vaccine?	
https://rbdcov.eu/partners/ PROJECTS Partners	Text -> Go to web	Go to web page	Recommendation
Contact	Press Office Contact us for general information Susana Garayoa sgarayoa@zabala.eu Phone number: M (+32) 484 61 91 64 (Brussels) Amaia Cabezón acabezon@zabala.es Phone number: M (+34) 673 744 542 (Pamplona)	Contact persons for trials should be defined at local level as well, in Turkey and Spain and contact for emergencies. Apart to provided telephone numbers, other communication channels to include (what's app, Viber) And to indicate contact hours	**Recommendation**
General information about clinical trials		To add one paragraph, mentioning that the patient has a right to withdraw from the study at any moment they decide to, as participation is completely voluntary.	**Suggestion**
General information about clinical trials		To add one paragraph, mentioning feedback to study participants from clinical trial implementers, should they expect any kind of feedback about successes/final results of study? If yes, in which form?	Clarification

RBDCOV Website Participant Q&A sheet

QUESTION	ANSWER									
	Current status	Answer	Bogdan	Deniz	Maka	Sieqi	Brian	Alain	Fiona	Julianna
Will my participation in the clinical trial be confidential and how will my privacy be protected?		Your participation in this clinical trial will be confidential throughout. The procedures we have follow strictly the national laswns on provacy and confidentiality. In addition, after the end of the study, we will annonymise (remove) the identifiable information about you so it will be impossible to us and anyone else looking into results to see who participated in the trial.		The sponsor and the centre, in particular, with regard to the processing of personal data and the free movement of these data, the Regulation (GDPR) of the European Parliament and of the Council (GDPR) of 27 April 2016 and No. 3/2018 of 5 December on the protection of natural persons and the protection of digital rights. will comply with the Organic Law and other regulations developed on the LOPDPGDD and data protection regulations within the framework of the data protection laws valid in Turkey.	Personal information of clinical trial participant to Protected Health Information (PHI), that ensurs its security. Disclosure of any personal information of the research participant without his/her consent is regulated by relevant laws. Before involving, pay attention to the participant Concent Form to be sure what information will be used for which purpose.					
			From the 19/08 meeting: Move to Privacy and Confidentiality (asnwer: ask the WP4 turkish clinical team to see what safeguard for protecting these they have)	I think this question can be considered as two separate questions. What do we mean by safeguards? The meaning of the word "safeguards" can be very broad. Participant Confidentiality, Personal Data Protection. - We can divide it into two titles as Participant Confidentiality and Personal Data Protection. Here too, since Turkey is not a member of the EU, it may be necessary to give detailed information accordingly in the answer. Move to Privacy and Confidentiality (asnwer: ask the WP4 turkish clinical team to see what safeguard for protecting these they have)						
What is a consent form/Written authorization?					Informed consent is the process of providing you with key information about a research study before you decide whether to accept the offer to take part. The process of informed consent continues throughout the study. To help you decide whether to take part, members of the research team explain the details of the study. If you do not understand English, a translator or interpreter may be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, how long it's expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits. You can then decide whether to sign the document. Taking part in a clinical trial is voluntary and you can leave the study at any time.					
If blood sample is taken, why?		We need to take some blood sample in order to asses the impact that our vaccine has on your body and overall health condition. (I feel that there is needed for better answer)		During the visits, a blood test will be performed, which will include a biochemical and hematological analysis to check your blood cells, liver and kidney function.41 ml (approximately 4 tubes i.e. 3-4 tablespoons) of blood will be drawn from all participants or 80 ml (approximately 8 tubes i.e. 5-6 tablespoons) if you are part of the subset where cellular response will be measured. Some of the samples will be retained for analysis that may be required in the future.						
What will happen to my medical care if I stop participating in the trial?			Comment to proposed question: I think this question is not necessery, since there is already a Q&A which states that there is no consequence in giving up the trial anytime throughout.		New question for your consideration					
What happens after a clinical trial ends?			I am pretty happy with Maka's proposed response.	After the completion of the study, your doctor will recommend the most appropriate vaccination strategy for you, based on the final results of the study. The sponsor works with a community advisory panel to ensure results are formally communicated in an appropriate language and that you can discuss them with the study team. No additional follow-up is envisaged at this point after the study is completed.	Once a clinical trial or study has ended, the researchers will collect and analyze the data to see what next steps are needed as a result of the findings. You may be able to access results of the research.				I like Deniz's answer, as otherwise it is general, I would also change the question to "what happens after the	
If the vaccine works for me, can I keep using it after the trial has ended? (as additional booster dose)					New question for your consideration					
What will happen with the results of my participation? How and when will I be informed about it?									This is partly answered in the above question: "what happens	
What are the ingredients in this vaccine?	Suggest the investigation team to propose their answer (ingredients or description of main ingredients) that is also understandable to the reader				Vaccines contain tiny fragments of the disease-causing organism or the blueprints for making the tiny fragments. They also contain other ingredients to keep the vaccine safe and effective.					
How many appointments will I have in this trial?	double check the frequency of appointments	There will be five or six appointments in total, depending on the geographic area where the trial happens. OR There are five total appointments in Turkey and 6 total appointments in Spain.	In both, the PIS and the protocol, there are only 5 visits specified: one for vaccine administration and four for follow up. I could not find six appointments anywhere, so no difference between Turkey and Spain *On-site follow-up visits will be performed on Days 14, 91, 182 and 365*							

How much time will I spend in the clinic/hospital/centre?	**Finished, but ask the clinical team to provide a rough estimate about how long it will last**	**There will be an initial longer appointment, to make sure you understand your participation in the trial. The following appointments should be shorter, depending on your personal details.**		For Turkey; "You will need to visit the hospital 5 times in total (one for volunteer selection and administration of the vaccine, and four for post-vaccine follow-up visits where safety, tolerability, and immune response to the vaccine are evaluated)."						
What safeguards are there to protect me during my participation in this clinical research?	Finished	The participant is monitored when the vaccine is administered and followed up throughout the trial by the clinical team. In the background there is an independent board, called the Data Safety Monitoring Board, who look out for unexpected events.								
How has this vaccine been developed?	Finished	As with all medicines, every vaccine must go through extensive and rigorous testing to ensure it is safe before it can be introduced in a country's vaccine programme. Each vaccine under development must first undergo screenings and evaluations to determine which antigen should be used to invoke an immune response. This preclinical phase is done without testing on humans. An experimental vaccine is first tested in animals to evaluate its safety and potential to prevent disease. If the vaccine triggers an immune response, it is then tested in clinical trials, in humans.								
How long is the trial going to last?	Finished	According to our planning, we estimate that the trial will last one year.								
Why should I participate?	Finished	Your participation you can contribute to science and help others. It will help us understand better how our investigational vaccine will work on people that get COVID-19. This vaccine is intended to work on people that have comorbidities - other diseases. If successful, we hope that the vaccine will give you a stronger immunity against serious symptoms that the virus may give you.								
What are eligibility criteria?	Finished	Eligible criteria are a set of conditions that allow you to participate in the trial, such as your age, vaccination status or general health status								
What is an open label study?	Finished	An open label study is one in which both, the participant, the clinician and the researcher know that the administrered medication is the study medication.								
Are there risks involved in participating this clinical trial?	Finished	In the unlikely event that unforseen experiences may happen, we have safeguard measures in place to ensure your safety.								
Is it possible to experience side effects during this clinical trial?	Finished	Every medication may have side effects. Most frequently reported side effects include sensitivity and pain at the injection site, fatigue/tiredness and headache for less than 72 hours, similar to a mild-moderate flu, without limitation of normal daily life activities. In case of any side effects, the person should contact the doctor or clincal team.								
Can I stop participating at any time?	Finished	Your participation is completely voluntary and it is up to you how long you feel comfortable to continue to participate. Although we encourage you to participate until the end of the trial, to collect all the relevant data, and we do our best to make sure that your participation is as safe as possible, you are always free to withdraw, with no consequences, if you no longer want to participate.								
Will I be compensated for participating in this clinical trial?	Finished	You will receive compensation for your time used for each visit, and to cover your transportation and travel expenses. The investigator team will tell you about the amount and expected schedule for payments								
Will I need insurance to cover my participation in this study?	Finished	No, this matter has been taken care by the clinical trial insurance.								
What will happen during the visits?	Finished	During the first visit, blood samples will be collected, the vaccine will be administered and we will provide you with instructions for the follow up meetings. During the follow up meetings, more blood sample will be collected and we will discuss any reactions you have had to the vaccine or answer any questions you may have.								

RBDCOV suggested terms for website Glossary

- Phase I to IV clinical trials
- Open-label trial
- Immunogenicity
- Recombinant protein (perhaps recombinant on its own too)
- Heterodimer
- Vaccine candidate
- SARS-Cov_2
- Immunosuppression (which is not only due to HIV)
- Immune responses
- Immune system
- CD4 count
- Dialysis
- Primary immunodeficiency
- Clinical investigator
- Variants
- Whole virus
- RNA vaccines
- Antigens
- Weakened virus
- Biobank
- Adjuvants
- Booster dose
- Antibodies
- Blood oxygen saturation
- Cellular immune response
- Biochemical and hematological
- Antigen test
- RT-PCR
- Rash
- Hives
- Community Advisory Panel (CAP)