RBDCOV Project

RBD Dimer recombinant protein vaccine against SARSCoV

D8.3 Report on Communication and dissemination activities – 2 - M24

PROJECT FUNDED BY EUROPEAN COMMISSION

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PU	Public	☒
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Document contributors

DELIVERABLE RESPONSIBLE

Contributors	Organization	Reviewers	Organization
Nora Franco	Zabala Innovation	Laura Sesma	Zabala Innovation
		Gisela Bigas	HIPRA
		Ivette Ballesteros	HIPRA

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Abbreviation	Term
Diss & Comm	Dissemination and Communication
KPI	Key Performance Indicator
SEO	Search Engine Optimisation

Executive Summary

The present document represents **Deliverable 8.3 – Report on Communication and dissemination activities** of the RBDCOV project. It has been developed as part of Work Package 8 – Dissemination and Communication.

The deliverable compiles the tools, actions, procedures and results of the dissemination and communication actions, achieved during the **second year of the project** (M13-M24).
The Plan has been deployed in three different phases:

- Building the RBDCOV **brand** (is completed).
- Putting in value **milestones,** progresses and achievements (in progress).
- **Disseminating** results (in progress).

During the second year of the project, we continued with the implementation of the Dissemination strategy. Initial actions, as showcased in the first report, were established during the first year. These actions included the design of the RBDCOV Brand, the creation of the website, and the setup of social media channels, building a solid ecosystem to ensure that all activities carried out under the project are easily recognizable.

We can summarize that we have successfully established a solid and coherent brand, characterized by its easy identifiability, a unified tone, and, importantly, by fostering a sense of partnership among all the partners. This has resulted in the appropriate usage of guidelines and channels by all partners.
Below, we will provide a more detailed explanation of the main progressions in the communication and dissemination plan carried out during the second year:

- **Ensuring the correct development and implementation of the RBDCOV brand**: both visually and tonally, by providing partners with all necessary reviews and materials such as templates and presentations.

- **Communication materials package**: considering the project's needs, a series of communication materials have been designed and distributed among partners. The goal was to support them not only in presenting the project coherently but also by providing specific materials to assist in achieving project objectives, such as the recruitment of volunteers.

- **Website and Social Media channels**: A digital marketing strategy has been designed with the aim of attracting as many visitors as possible to the RBDCOV website. Contents and news are regularly updated, focusing on highlighting the project's milestones, achieved advances, and results. This includes promoting our participation in events and establishing connections with the key target audiences defined in the Dissemination & Communication Strategy.

- **Media Engagement:** Promoting the project's presence in media outlets by sharing key press milestones, through the distribution of press releases to both mass and specialized health media, and publishing articles and news pieces to inform about the project's advancements.

- **Event Participation:** Promoting RBDCOV's presence through participation in scientific events and other events of interest with the aim of raising awareness about RBDCOV and clustering collaboration with other EU projects.

- **RBDCOV Talks:** A podcast strategy has been defined, encompassing objectives, a content and distribution plan, and a distinctive sound and visual identity. These actions have been developed with the aim of innovating in the way we raise awareness about the project. It is also aligned with the objective of making technical concepts of the project more accessible to a wider audience.

In addition, this document includes an annex dedicated to **press clippings** on the project and news related to the project, as well as **the scripts** created for the RBDCOV podcast, **RBDCOV Talks**.

Approach of the Dissemination and Communication strategy implementation

1.1. Communication and dissemination plan, channels, and activities

Table 1. Diss & Comm actions

Means	Description	Stage
Logo and presentations	Logo and presentation template for all partners.	DONE
Project website and positioning	Project's website, providing information about the project, development, showcasing project's news and acting as a communication hub.	DONE; in process
Videos and multimedia	1 video presenting the project	DONE
Social media channels	Twitter and LinkedIn accounts. Working in building communities and preparing good content.	DONE, in process
Communication material	Ad-hoc information for events	DONE, On going
Written content	Articles, news, and interviews will be produced and distributed to the media, specialised press, health websites, and other relevant information outlets.	On going
RBDCOV events	1 final event at the European Parliament	M30

The **task 8.1** is leaded by Zabala Innovation and needs the participation and collaboration of all the partners to succeed.

The **D8.1 Project website describes the website** (www.rbdcov.eu), how it works, which kind of materials are going to be updated there and the different contents.

The **D8.2 Plan for the Exploitation and Dissemination of Results (PEDR)** sets the strategic communication and dissemination -as well as the exploitation- plans to answer who will receive what key messages, how and when they are going to receive them. It was used to create a time planner to control how the project will develop in the upcoming months.

The **D8.3 Report on Communication and dissemination activities** compiles the tools, actions, procedures and results of the dissemination and communication actions, achieved during the first 12 months of the project.

1.1. Project identity

The RBDCOV identity was created in the first year of the project and has been maintained ever since. This identity establishes the visual guidelines of the project, including templates for documents, the correct implementation of the logo – specifying both correct and incorrect uses, and the prescribed brand colors and fonts.

As a cohesive brand, this identity has been implemented across all actions and channels, including the website, social media profiles, and communication materials as elaborated in the following points:

1.1.1. RBDCOV Brand

The logo and visual identity created during the first year make the project distinctive and recognisable, while having a personality that reflects its goals. To maintain a cohesive representation of RBDCOV, all guidelines established with regards to the application of the logo, colours and typography have been conveniently followed and applied to all the tools created related to the project, from the external materials /such as presentations, brochures, social media or website) to all internal documents of the consortium members and stakeholders.

Among the actions that have taken place throughout the second year, the broadcast of a dedicated podcast (RBDCOV Talks) is the clearest example of how the development of the project's identity and brand image has continued during the months covered by this report.

To ensure proper implementation, a series of templates have been designed and distributed among the partners. Additionally, all public documents have been reviewed by the communication team to ensure correctness.

Both, the official brand guidelines manual and the templates have been communicated and made available to the consortium partners. They are also available on the website to make them accessible to the communication departments and the public.

1.2. Social Media Strategy

Since the first year of the project, RBDCOV profiles on social media, including Twitter and LinkedIn, have been created to enhance the visibility of the project and its results, attracting the interest of stakeholders and the public. Social media profiles also serve as valuable tools to generate more visits to the website and support the partners' goals by disseminating information about their results, utilizing these channels to achieve the objectives of their work packages.

To maintain and enhance the social media profiles, a comprehensive monthly calendar has been created and reviewed by the coordinator and EATG, the partner responsible for community engagement.

Furthermore, we have actively listened to the needs of the project, creating ad-hoc campaigns that will be detailed in the following lines:

1.2.1. Social Media Campaigns

- **Project** Milestones:

The social media profiles have served to highlight and celebrate the milestones of the project, such as:

- The recognition of the Spanish Prime Minister for the BIMERVAX vaccine. Refer to the example below, and click here to view the published post:

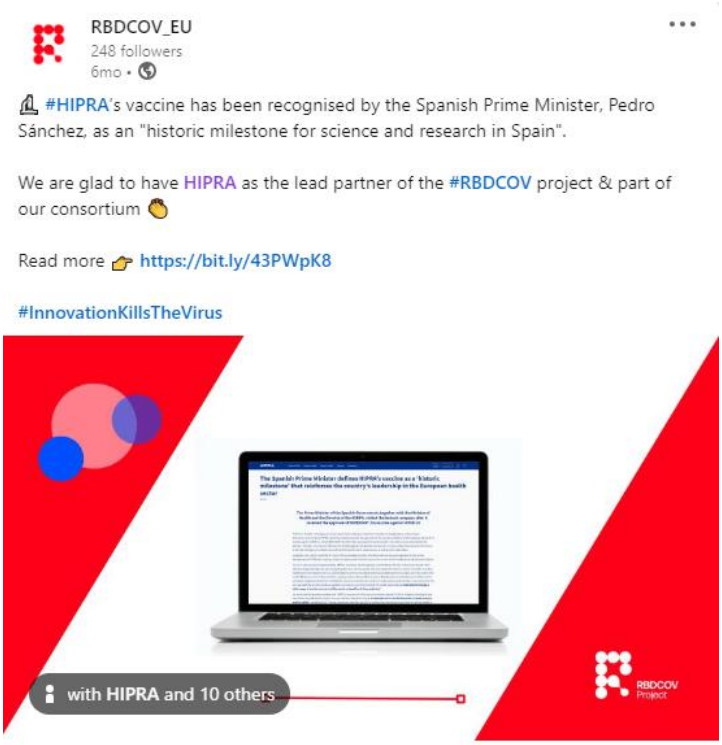

Figure 1: Social Media Post promoting a Milestone of the project

- The authorization of the clinical trial in adolescents by the European Medicines Agency (EMA). Refer to the example below, and click here to view the published post:

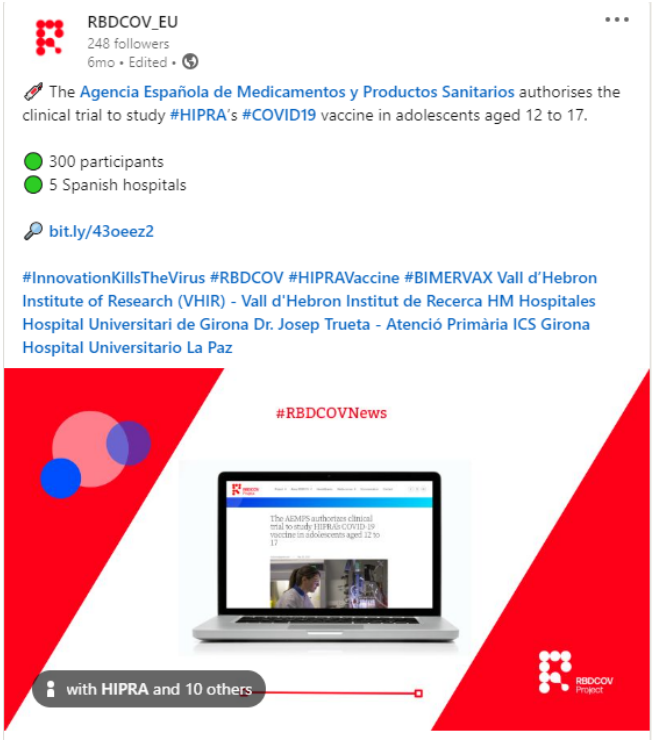

Figure 2: Social Media Post promoting a Milestone of the project

- The face-to-face meeting with the members of the community advisory, EATG, and HIPRA's team. Refer to the example below, and click here to view the published post:

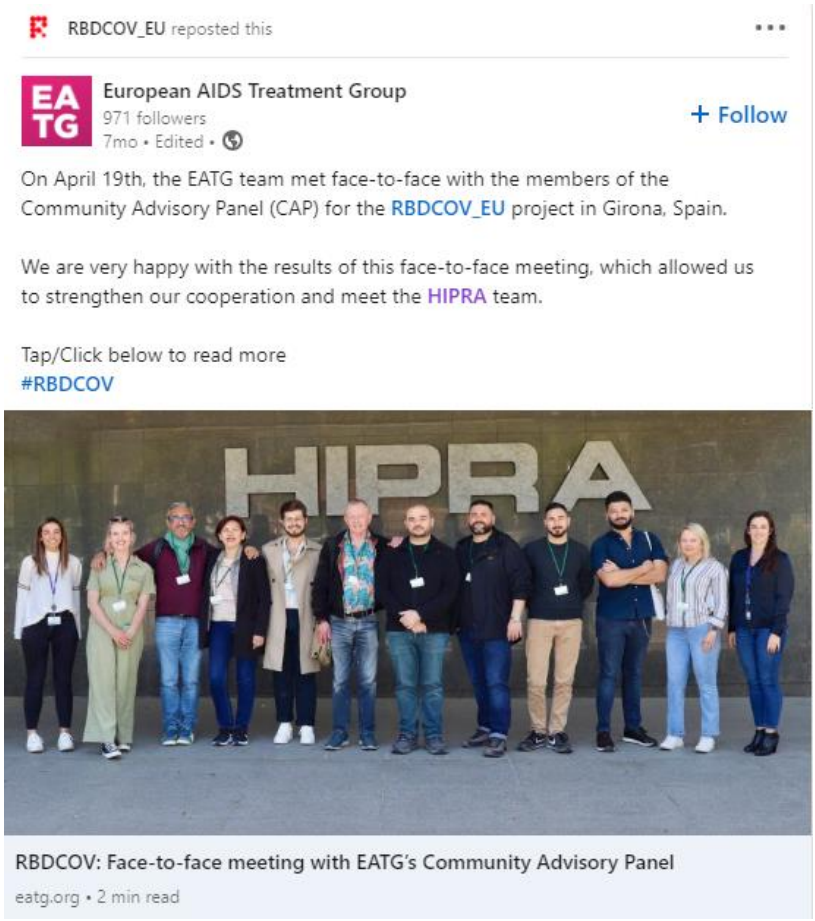

Figure 3: Social Media Post promoting a Milestone of the project

- The research meeting led by one of our partners, IRSICAIXA. Refer to the example below, and click here to view the published post:

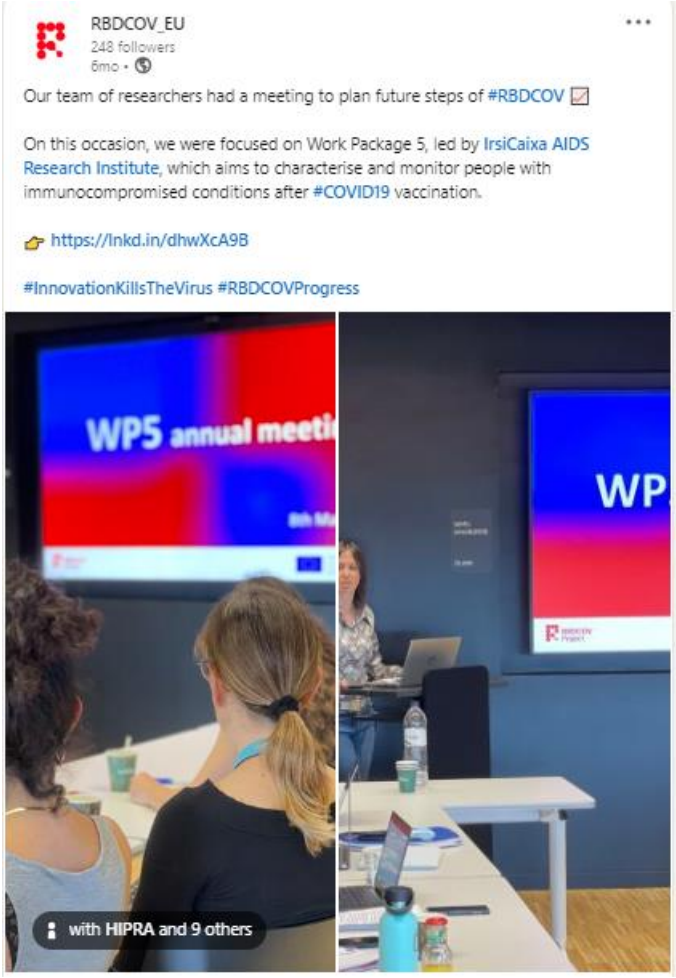

Figure 4: Social Media Post promoting a Milestone of the project

These are only a few examples in which the social media profiles serve to amplify the dissemination of the project's achievements.

Additionally, a social media campaign highlighting the main milestones of the project was launched. To achieve this, we conducted a comprehensive review of all project milestones, including the HERA signature, approval, and AEMPS authorization for the clinical trial to study HIPRA's COVID-19 vaccine in adolescents aged 12 to 17. For the campaign, we used the hashtag #RBDCOVMilestone.

The objective of this campaign is to provide a comprehensive overview of the project's progress.

This allows our key target audience to track the project's developments at a glance. See the post below with the milestones presented during the campaign, and click here to view the published post:

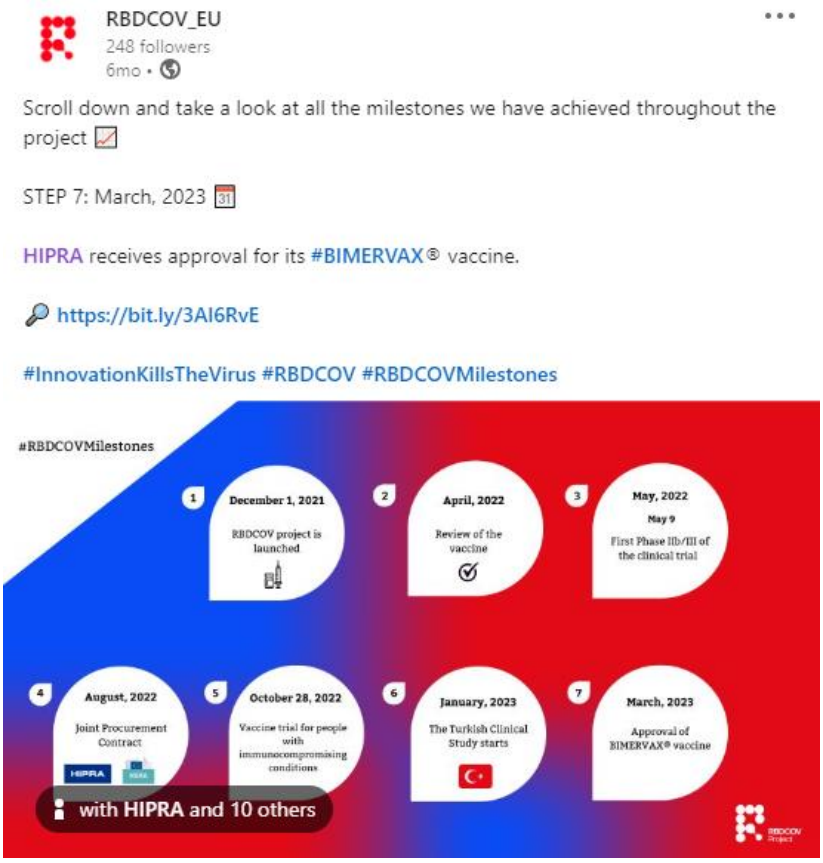

Figure 5: Social Media Post Milestones Campaign

- Refer the post below as an example of one of the milestones, and click here to view the published post:

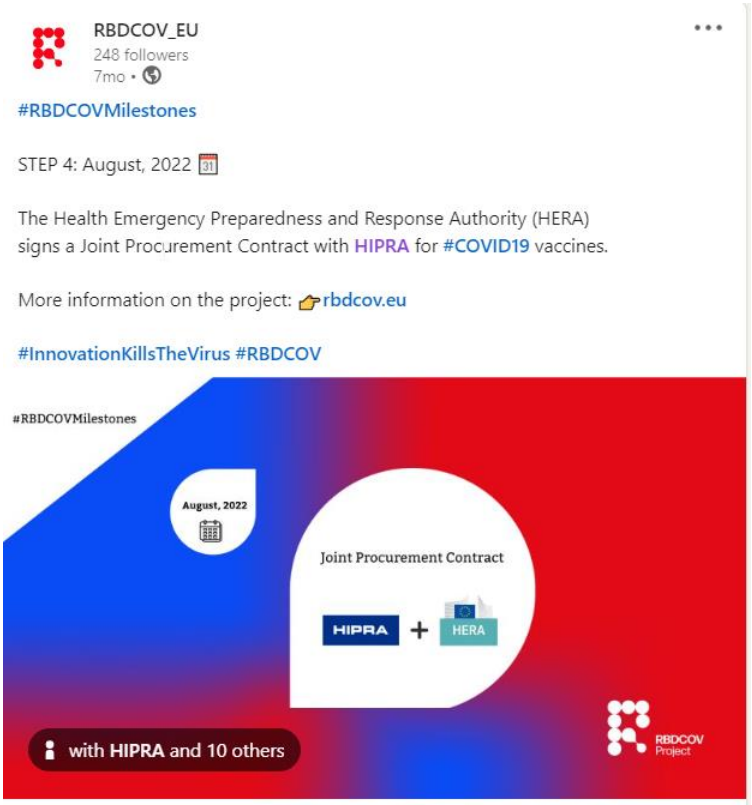

Figure 6: Social Media Post Milestones Campaign

- **Ephemerides:**

  The ephemerides related to the health sector and vaccination have been used to position the project, highlighting its objectives, mission, and commitment. See below some examples of ephemerides; we have taken into consideration the following ones:

  - 11-Feb: International Day of Women and Girls in Science
  - 07-Apr: World Health Day
  - 24-28 Apr: World Immunization Week
  - 20-May: International Clinical Trials Day
  - 17-Sep: World Patient Safety Day
  - 09-Nov: International Day of Science and Peace
  - 01-Dec: World AIDS Day
  - 12-Dec: International Universal Health Coverage Day
  - 27-Dec: International Day for Epidemic Preparedness

- See as examples, the four posts below referring to #InternationalClinicalTrialsDay, #WorldImmunizationWeek, #WorldPatientSafetyDay and #WorldScienceDay

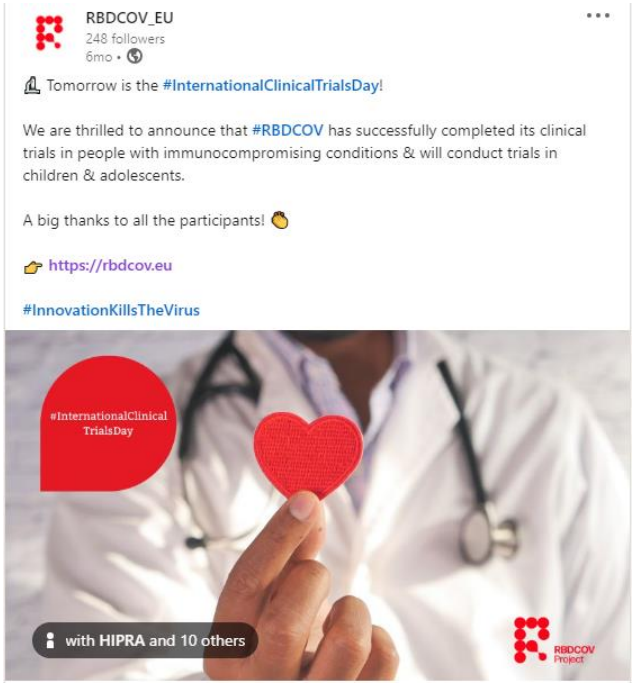

Figure 7: Social Media Post - Ephemerides Campaign

Figure 8: Social Media Post - Ephemerides Campaign

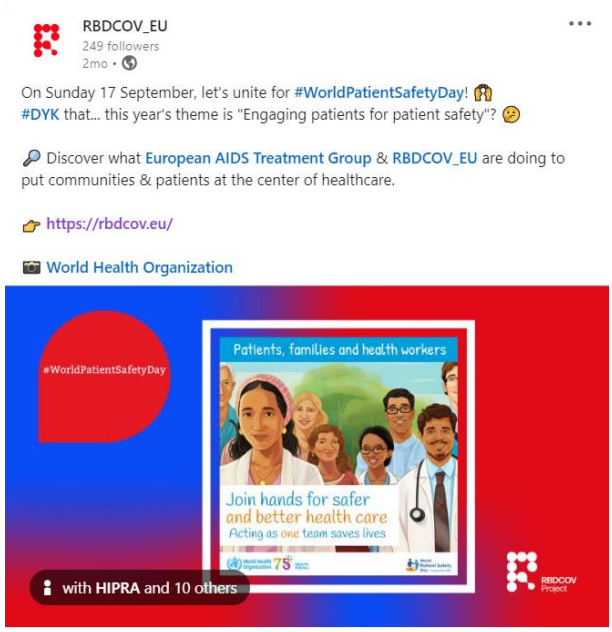

Figure 9: Social Media Post - Ephemerides Campaign

Figure 10: Social Media Post - Ephemerides Campaign

- **Partners Presentation - The role of the partners in the RBDCOV project:**
  Going deeper into the role of the partners, showcasing the expertise behind the project. See the two posts below: the first one, in which we present all the partners, and the second one as an example post in which we explain the role of Vall D'Hebron Institute of Research. This individual post has been published for each of the 13 partners.

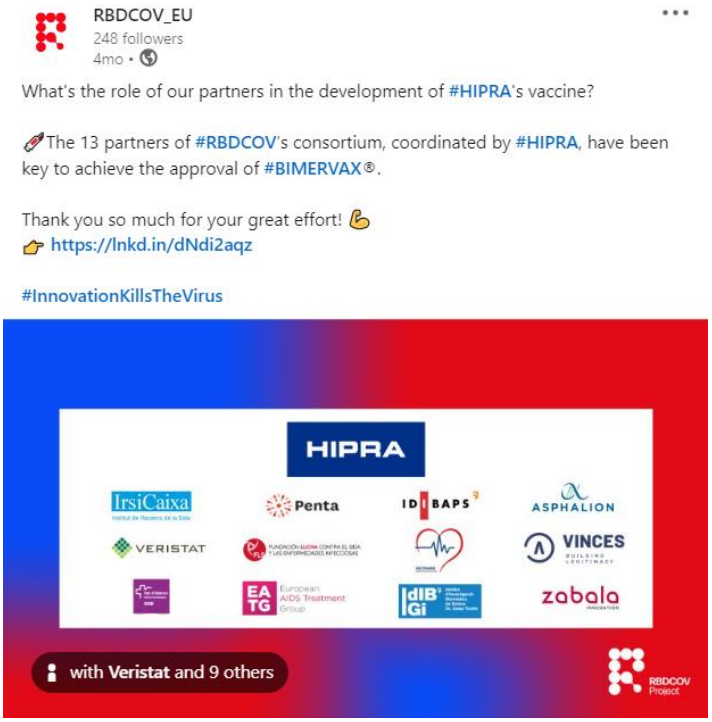

Figure 11: Social Media Campaign - Partners Presentation

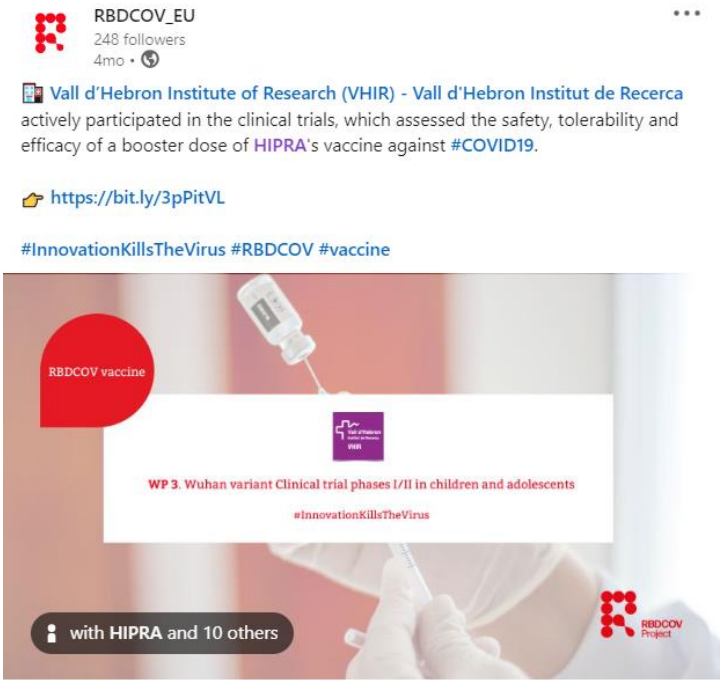

Figure 12: Social Media Campaign - Partners Presentation

- **FAQs:** We have observed that transparency is essential for building trust in the project and promoting participation in the clinical trials. For that reason, a social media campaign aimed at clarifying technical concepts and explaining how the clinical trial works is crucial. In this campaign, we have been breaking down frequently asked questions. Click on the image to view the published post.

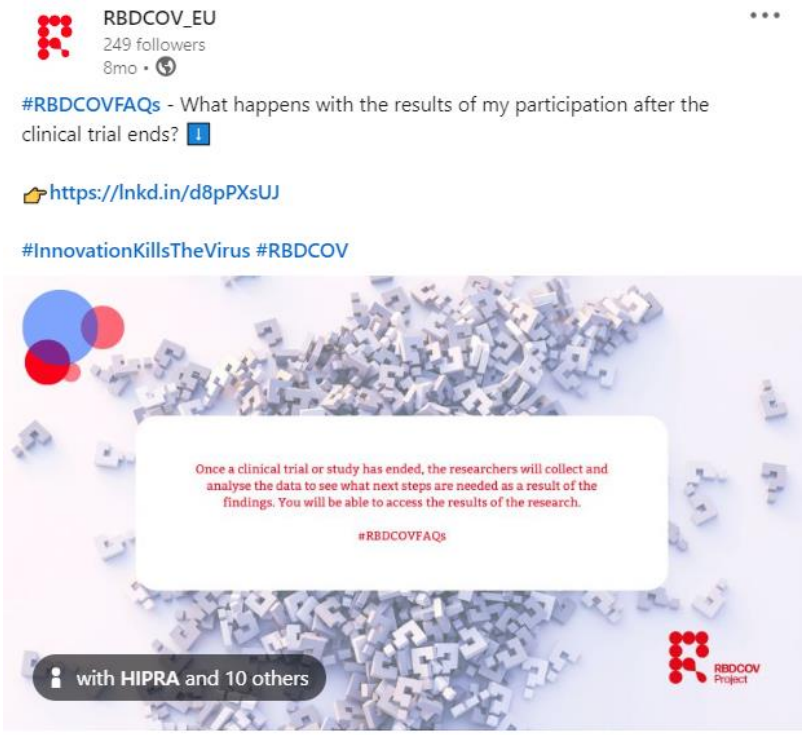

Figure 13: Social Media Campaign - FAQs

- **A Vaccine Mission – The Comic Expectation Campaign:** Presenting the individual cartoons progressively until unveiling the complete story. Click on the images to view the published post.

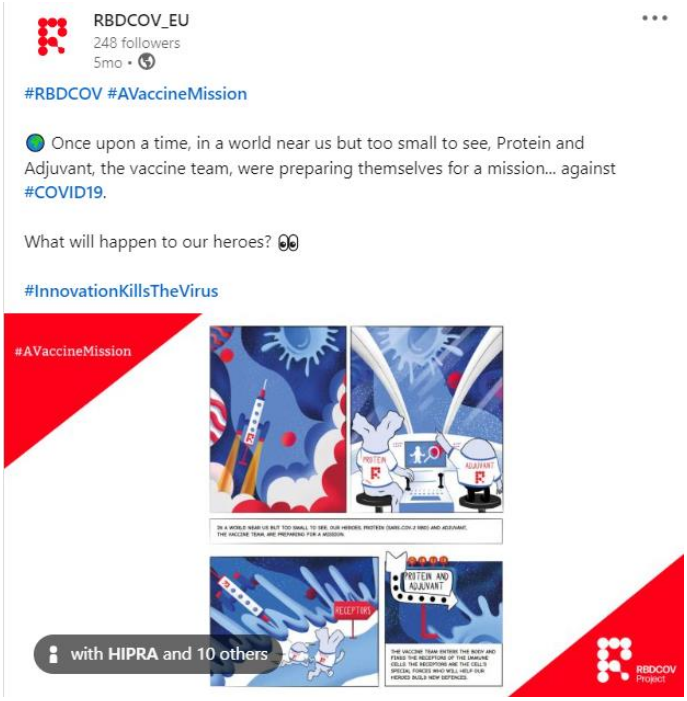

Figure 14: Social Media Campaign - A vaccine mission

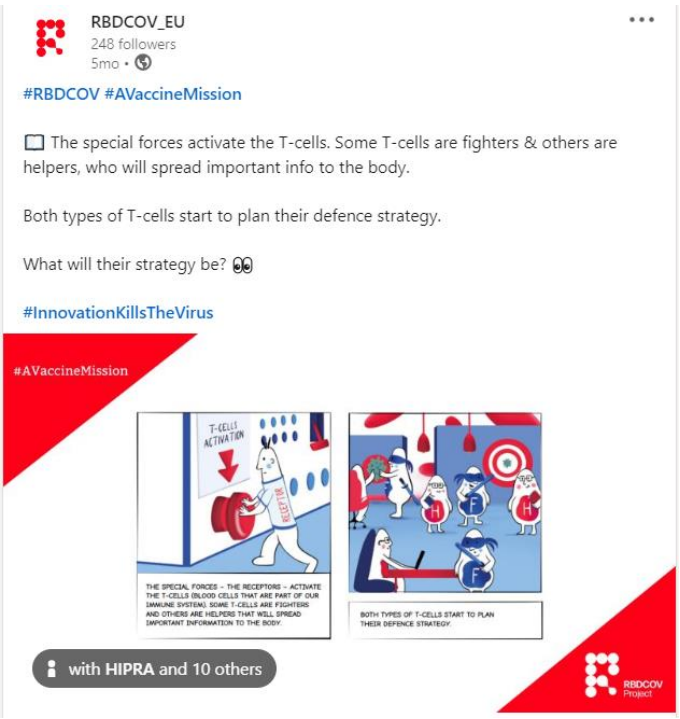

Figure 15: Social Media Campaign - A vaccine mission

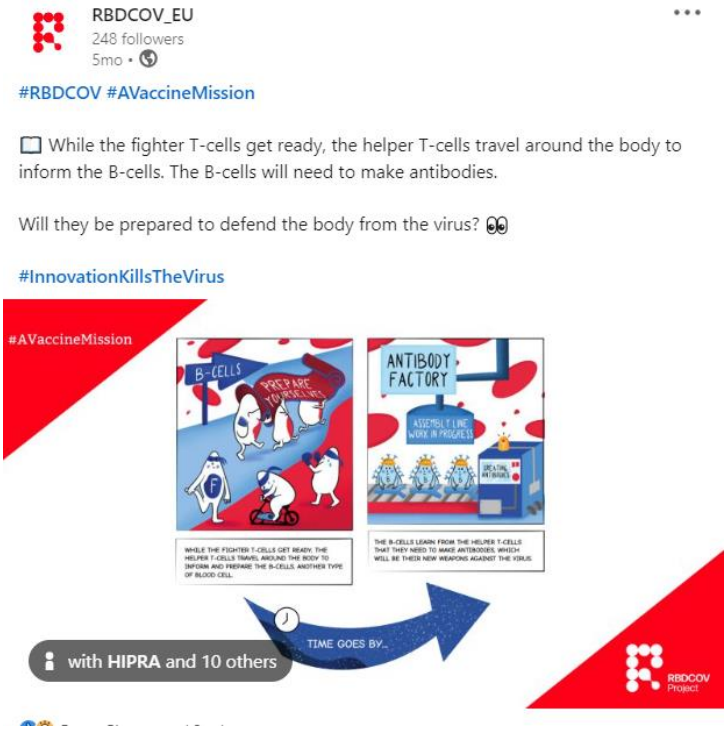

Figure 17: Social Media Campaign - A vaccine mission

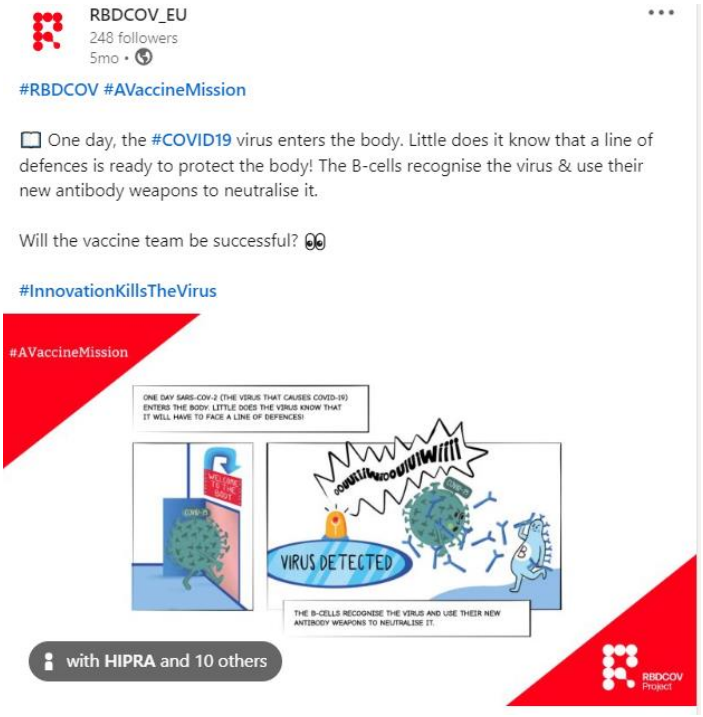

Figure 16: Social Media Campaign - A vaccine mission

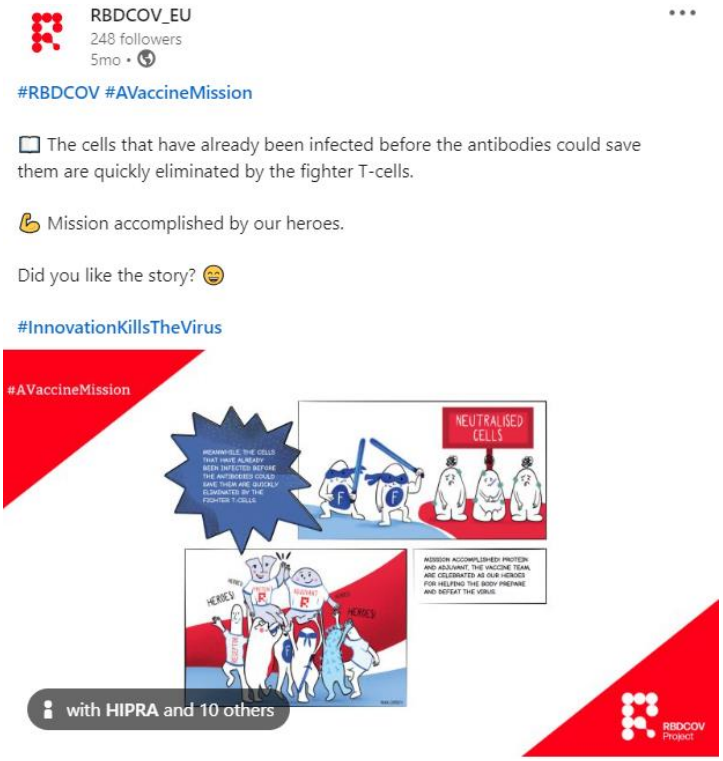

Figure 19: Social Media Campaign - A vaccine mission

Figure 18: Social Media Campaign - A vaccine mission

- **Supporting Clinical Trial Recruitment:** See below our own post providing information about the hospitals where the clinical trial is taking place and a repost from Vall d'Hebron.

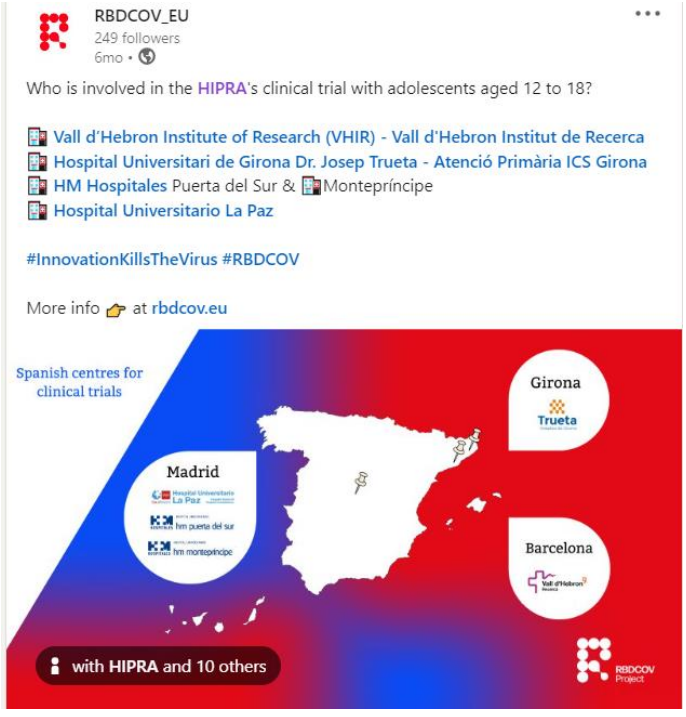

Figure 20- Social Media campaign - Clinical trial

Figure 21: Social Media campaign - Clinical trial

- **In COVID conversations – WATS:** In collaboration with VINCES, we use WATS, a tool designed to monitor conversations on Twitter. We have defined specific keywords for the project: RBDCOV, COVID, vaccination, immunocompromised individuals, and children and adolescents in relation to COVID vaccination. The reports provided by WATS (An example can be found below) enable us to create content based on trends and actively participate in the conversation, thereby positioning the RBDCOV project. With this tool, we identify and follow key stakeholders. A list of stakeholders has been created and complemented with contributions from HIPRA and the partners. See below two posts in which we quote key stakeholders of the project, such as The Lancet or the Minister of Health, Jose Miñones. Click on the images to view the published posts.

Figure 22: Social Media Campaign - In COVID conversations – WATS

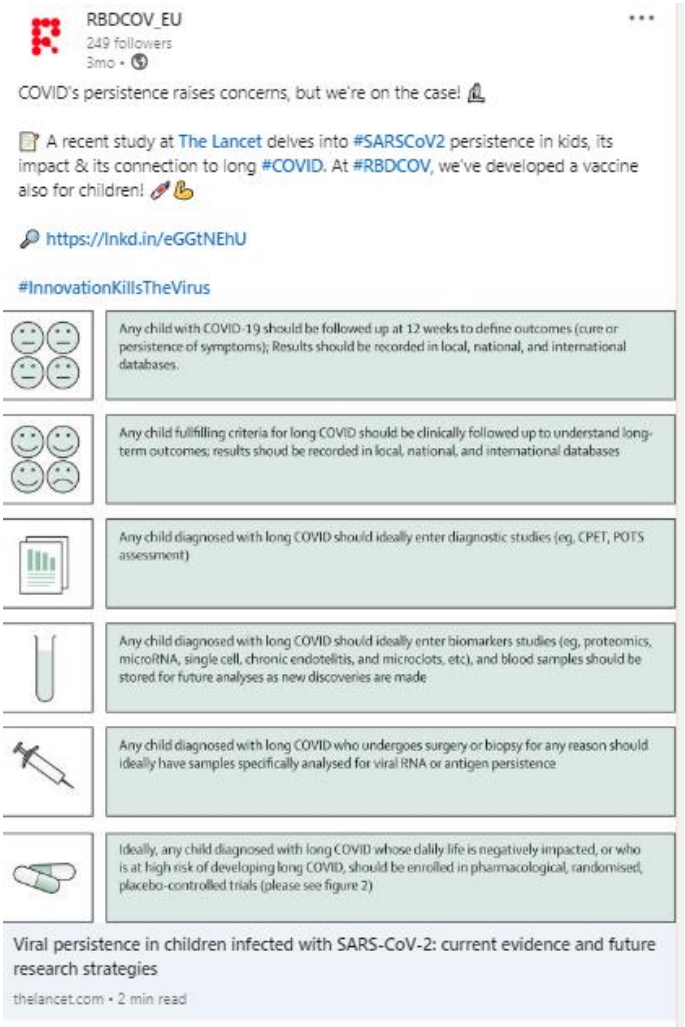

Figure 23: Social Media Campaign - In COVID conversations – WATS

See below the page of the WATS report corresponding to the month of August and the mentioned tweet:

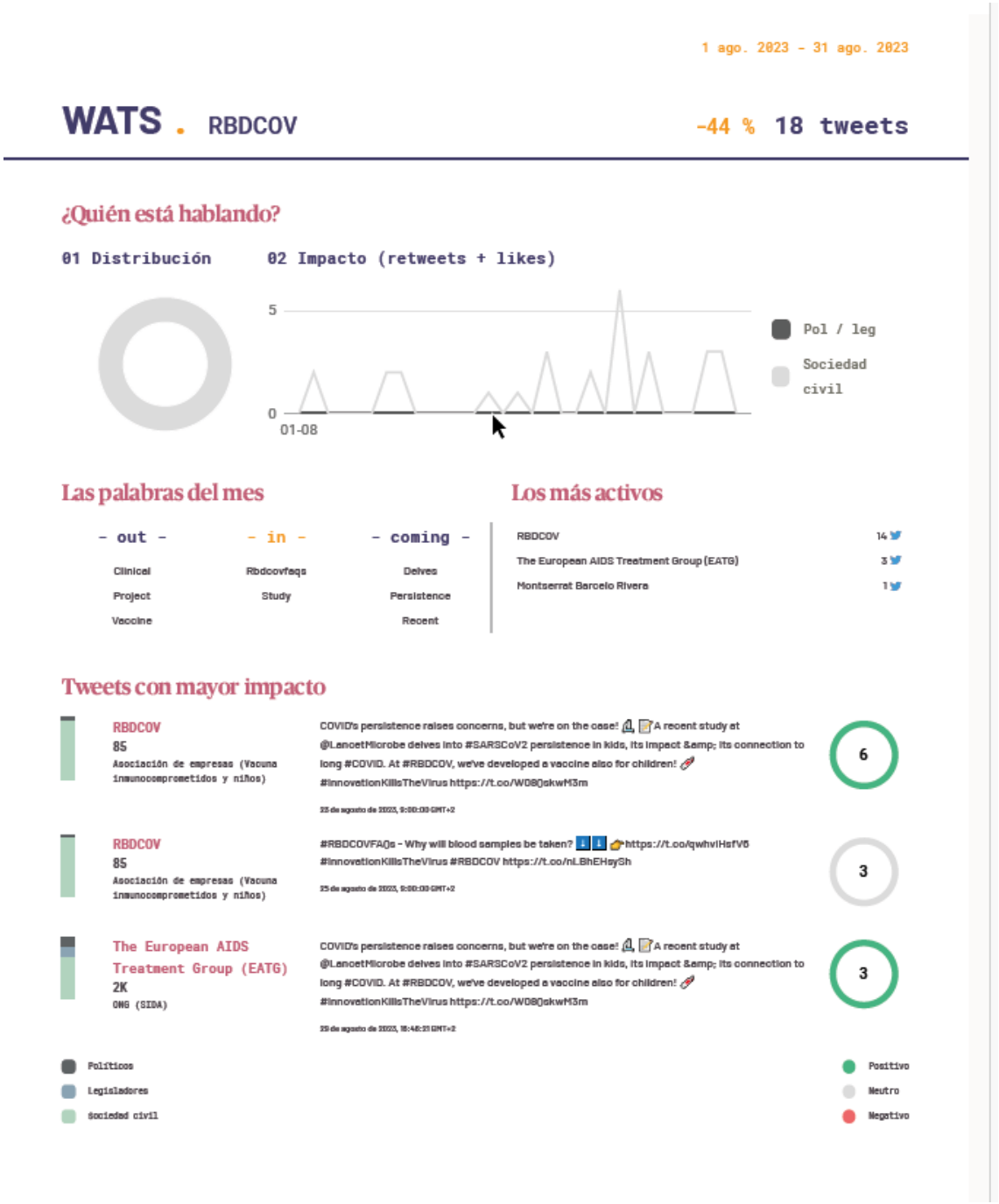

Figure 24: WATS Report - August 2023

- **Specialised articles promotion:** The social media channels have also served to disseminate specialized articles prepared by the partners, in which a key topic of the project has been explained in a clear and accessible manner. See below the post promoting the specialized article by ASPHALION – How are vaccine clinical trials regulated, and how are ours regulated?

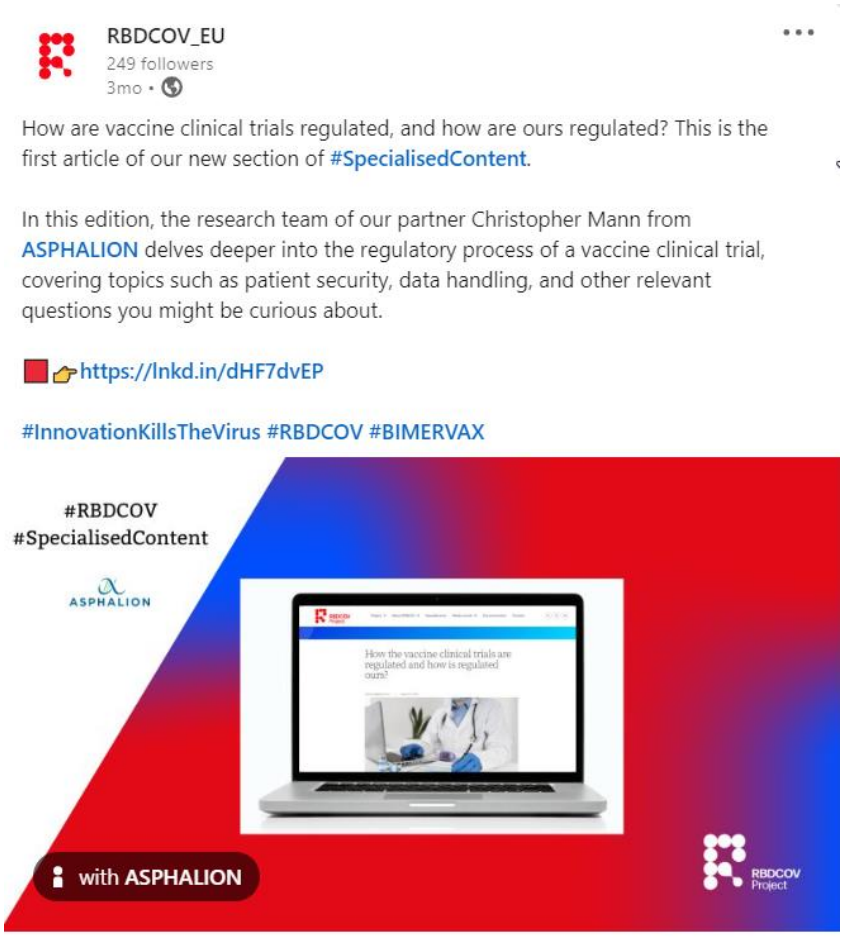

Figure 25: Social Media Campaign - Specialised articles promotion

1.2.2. Twitter

The credentials for Twitter are the following:

- @RBDCOV_EU – handler
- #RBDCOV, #InnovationKillsTheVirus – hashtags

1.2.2.1. Twitter analytics

On Twitter, the project has a total of 105 followers (31 new followers compared to the previous period, representing a 42% increase). The total number of posts on the profile to date is 389 (188 new posts compared to the previous period). **On LinkedIn, the number of followers is 248** (80 new followers compared to the previous period), and a total of 142 new publications during the course of 2023.

Twitter

2023: **105 followers**

Trimester 2023	Impressions	Engagement rate
January-March	12,1K	3,2%
Abril-June	12,1K	5,5%
July-September	7,7K	3,3%
October-November	4,3K	3,2%
AVERAGE	**9,05 K**	**3,8%**

Figure 26. Twitter main analysis over 2023

The total number of impressions[1] reached to date on RBDCOV's Twitter account is over 36,200, more than triple the number of the first period reported (10,600). Part of this increase is due to a growing number of followers, and therefore the content being shown to a wider audience.

As for the Engagement rate[2], it tracks how content resonates with the audience: engagement rate, link clicks, retweets, and likes. In the case of RBDCOV, the **average engagement rate is 3.8%.** In Twitter, most would consider 0.5% to be a good engagement rate, with anything above 1% great.

In 2023, the number of interactions on RBDCOV's social media accounts has remained high over the course of the past 11 months, with **an average of 110 impressions per day.** January stands out with a record number of impressions: 7,500 in total, which means an average of 241 impressions per day during that month. This upturn coincides with the date of the second meeting of the consortium in Barcelona, where the next steps of the project were defined.

[1] Impressions are the number of times the tweet has appeared on a timeline, which includes appearances on a follower's timeline, within Twitter's search platform, or on followers of followers' timelines. More simply, if a tweet has 1,000 impressions, it has been seen 1,000 times.

[2] The engagement rate is the number of engagements (times a user interacted with a Tweet) divided by impressions.

Figure 27:Twitter post (January, 2023). A publication with over 2,600 impressions

1.2.3. LinkedIn

The credentials for LinkedIn are the following:

- @RBDCOV_EU – handler
- #RBDCOV, #InnovationKillsTheVirus – hashtags

The RBDCOV LinkedIn page establishes a public image on a global professional level as a reputable and reliable project. It is the business-oriented side of social networking sites, where the audience is more professional. Most of the followers have job functions like “researchers”, “Information Technolgy” (see below). This is aligned with the target groups established in the C&D strategy:

1.2.3.1. LinkedIn analytics

RBDCOV currently gathers 248 followers on LinkedIn (**+47% compared to RBDCOV's first report figure)** after a continuous and progressive increase over the course of the project. Just as with Twitter, this ensures that the content is shown to a wider audience on this network, where a professional approach prevails. This network allows RBDCOV to connect and attract the attention of professionals in the fields of health, research and science.

LinkedIn

2023: **249 followers**

Trimester 2023	Page views	Unique visitors
January-March	280	80
Abril-June	147	53
July-September	153	55
October-November	149	60
AVERAGE	**182**	**62**

Figure 28. LinkedIn main analysis

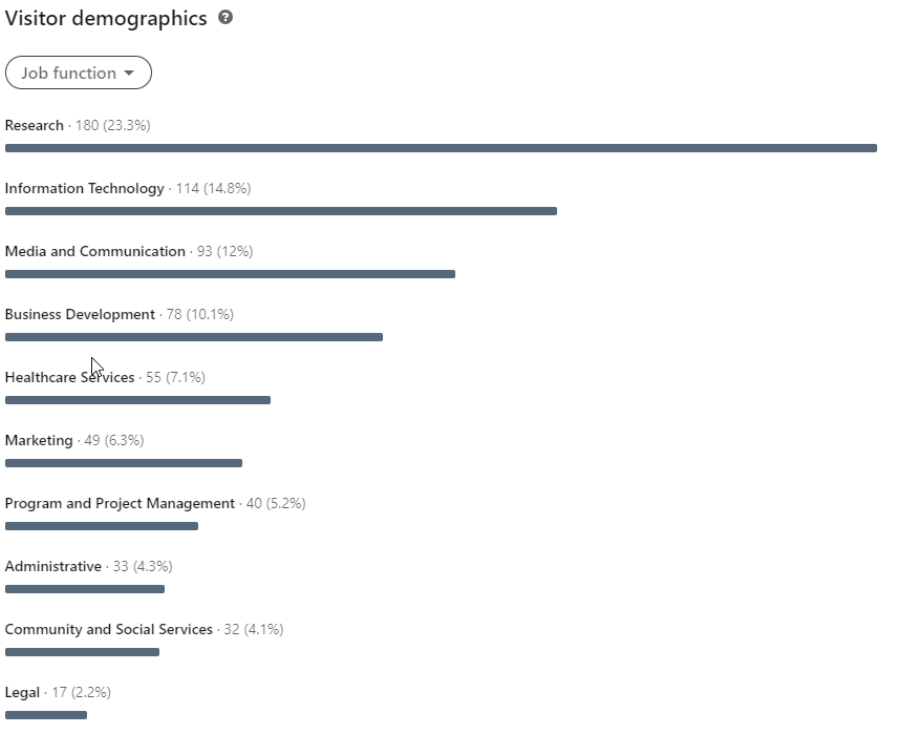

Figure 29. Top job functions of the LinkedIn followers

1.3. Project website

Inside RBDCOV website (www.rbdcov.eu) We can find:

- General information about the project.
- Description of all the organizations members of the consortium.
- Work Packages.
- Information about general clinical trials.
- Information about our two clinical trials.
- FAQs for participants.
- News and events section with all the details.
- Documentation section where all can find the public deliverables.
- Press releases and press clippings.
- All the visual identity material about the project.
- Contact page.

Here you can see the different pages created to keep everyone informed about all the information around the project.

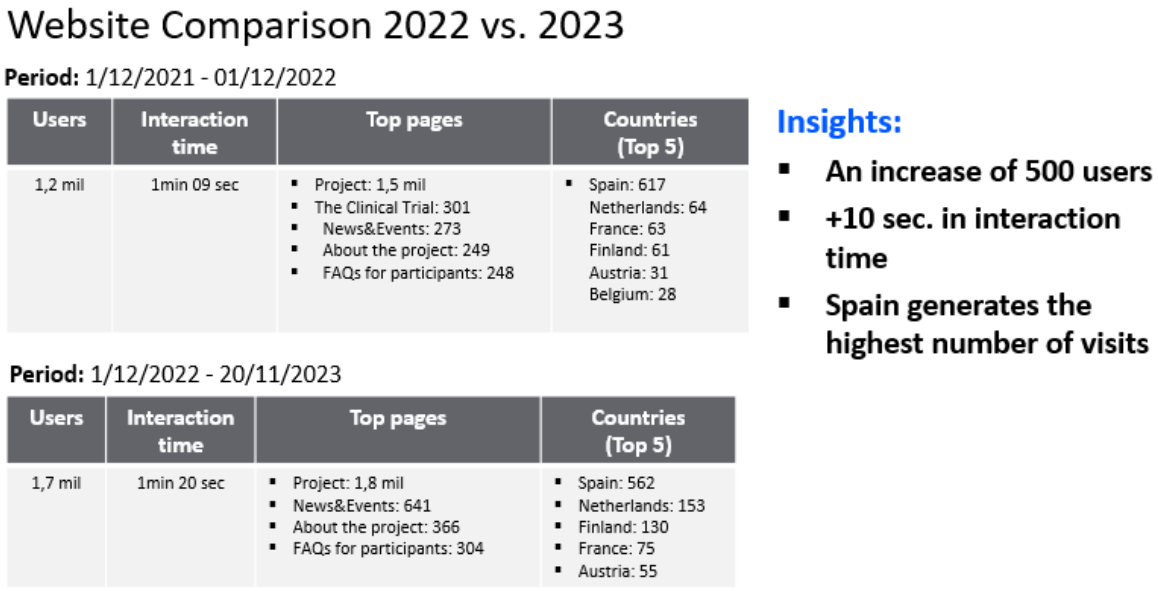

Figure 30: Website comparison 2022 vs 2023

1.3.1. Website evolution

The website has served to reflect the evolution of the project, updating it constantly according to the needs of the project, specially the Home Page and News and Articles section. Additionally, a new section has been developed with the aim of collecting a FAQs section for the current clinical trial in children and adolescents. This content has been provided by the EATG partner and reviewed by HIPRA.

A glossary has been implemented with the aim of clarifying key concepts for the project. Both the FAQs and the Glossary are available in the main languages of the project: English, Spanish, Catalan, and Turkish.

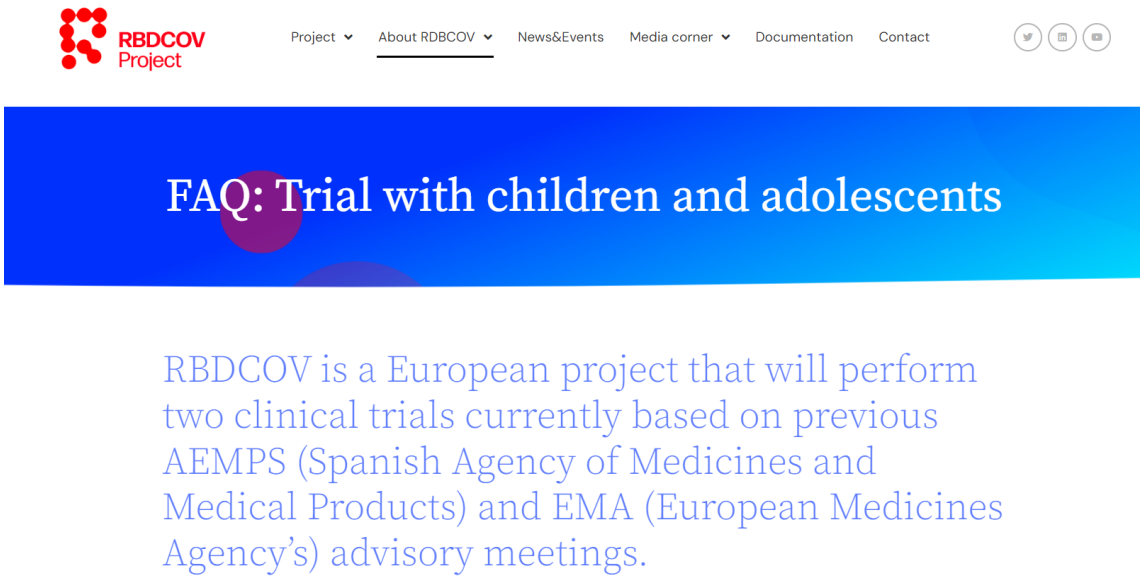

Figure 31: FAQs page - Trial with children and adolescents

Figure 32: Website Glossary

1.3.1.1. Web traffic

In the course of 2023, the project's website has reached **a total of 1,700 page visits, an increase of 42% over the previous period**. This represents **a total of 2,800 visits since the website's launch**. In terms of audience breakdown, Spain remains in the lead due to the fact that the clinical trials are taking place in this country, more precisely in the cities of Catalonia and Madrid.

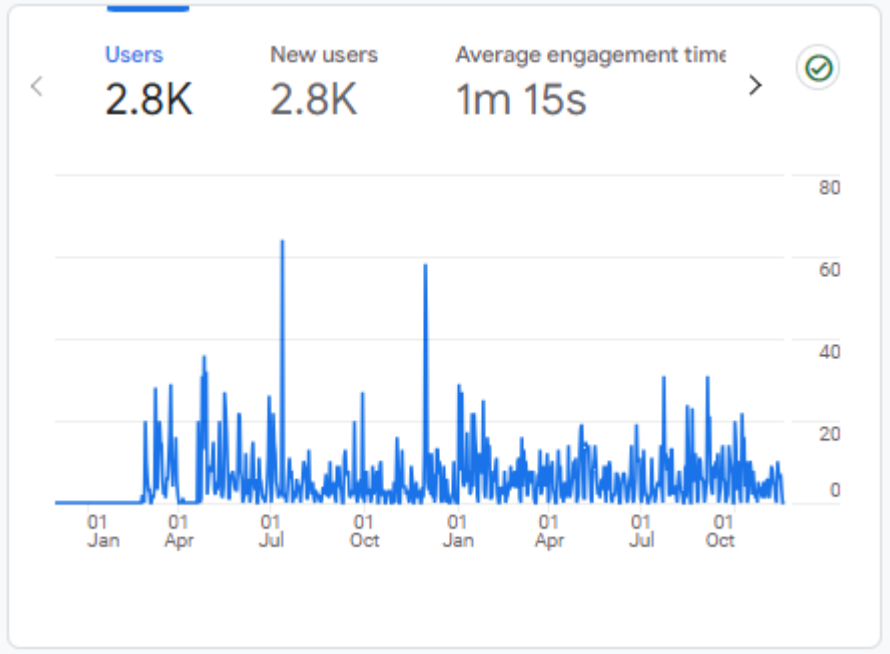

Figure 33: Website traffic. Time period: 01/12/2021 – 20/10/2023.

1.3.1.2. Web content

As for the most visited pages, the trend of interest is maintained in general terms, especially in the 'News and Events' section, where the most recent updates and the project's most important news can be consulted. Also noteworthy is **the growing interest in the 'FAQs for participants' page**, which has been progressively expanded with more content of interest to the audience. The result is not only an increase in the number of visits but also the page with **the longest average time spent reading: 1 minute and 27 seconds.** This page retention demonstrates the interest of the audience and the usefulness of this section to inform patients and, ultimately, to try to contribute to greater participation in clinical trials.

Pages & Screens
01/12/2021-20/11/2023

Pages	Visits	Users	Average interaction time
Home	2213	1028	33s
News & Events	687	150	45s
About	417	171	52s
FAQs for participants	399	211	1min 27s
The clinical trial	363	208	50s
Expert articles: How does the recombinant protein vaccine work	290	222	17s
About	264	138	27s
Documentation	226	121	10s
Partners	218	129	33s
Expert articles: How the vaccine clinical trials are regulated	167	113	1min 4s

Table 2: Most viewed Pages & Screens. Time period: 01/12/2021 – 20/10/2023.

News & articles

(From Feb 22 to Nov 23)

Pages	Visits	Users	Average interaction time
Infographic: how-does-the-recombinant-protein-vaccine-work	295	225	26s
Expert articles: how-does-the-recombinant-protein-vaccine-work/	155	110	1min 3s
News: Joining-efforts-to-further-advance-the-development-of-hipras-covid-19-vaccine	131	67	1min 49s
News: hipra-receives-approval-for-its-bimervax-covid-19-vaccine-a-stepping-stone-for-the-work-of-the-rbdcov-project	121	71	37s
Comic: rbdcov-a-vaccine-mission	123	55	32s
News: hipras-covid-19-vaccine-trial-in-people-with-immunocompromising-conditions-was-launched-in-turkey	104	63	32s
Expert articles: how-vaccine-clinical-trials-work	139	83	44s
News: towards-more-inclusive-and-representative-clinical-trials-interview-with-bogdan-hadarag-eatg-member	78	55	15s

Table 3: News & Articles. Time period: Feb 2022 to Nov 2023

News & articles

(From Feb 22 to Nov 23)

Pages	Visits	Users	Average interaction time
Infographic: how-does-the-recombinant-protein-vaccine-work	295	225	26s
Expert articles: how-does-the-recombinant-protein-vaccine-work/	155	110	1min 3s
News: Joining-efforts-to-further-advance-the-development-of-hipras-covid-19-vaccine	131	67	1min 49s
News: hipra-receives-approval-for-its-bimervax-covid-19-vaccine-a-stepping-stone-for-the-work-of-the-rbdcov-project	121	71	37s
Comic: rbdcov-a-vaccine-mission	123	55	32s
News: hipras-covid-19-vaccine-trial-in-people-with-immunocompromising-conditions-was-launched-in-turkey	104	63	32s
Expert articles: how-vaccine-clinical-trials-work	139	83	44s
News: towards-more-inclusive-and-representative-clinical-trials-interview-with-bogdan-hadarag-eatg-member	78	55	15s

Table 4: News & Articles. Time period: Feb 2022 to Nov 2023

1.3.1.3. Web Acquistion

An indicator of the success of RBDCOV's social media strategy has been the shift in the source of 'New users'. Specifically, it is noteworthy how 'Organic Social' now ranks in second place, surpassing Organic Search. This means that a greater number of visitors access the website through social media channels organically (without the influence of paid ads). This traffic corresponds to clicks by users on the content, more specifically, the URLs, about RBDCOV shared on social media. On the other hand, Organic Search refers to traffic that comes from search engine queries such as Google searches. In this case, the user conducts a search on these engines and clicks on the results generated by that search, also organic (meaning not paid to appear among the results).

The fact that RBDCOV appears in top positions for search results is due to the adherence to good SEO (Search Engine Optimization) practices. Among other factors, the terms and keywords that enhance the positioning of this page have been maintained, even expanding as new content is published on the website and search engines index it as new content available on the internet.

Direct traffic remains, as it is common, in the first position. These are users who access the website by typing the page's URL directly into the browser or using bookmarks (links they have saved for immediate access). This is, among other things, a sign of familiarity with RBDCOV's brand, which becomes more known and recognized by the audience as the project progresses, leading users to visit the website

directly. The referral category, in the last position, refers to people who access the project's website through a source or origin other than Google. This catefory also includes other websites that refer/link to the website project, for example media or other specialised websites

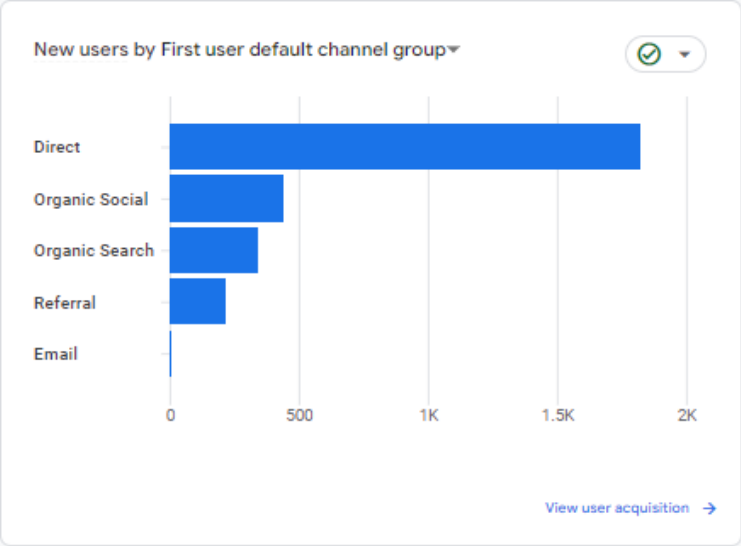

Figure 34: New user origin. Time period: 01/12/2021 – 20/10/2023.

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1.4. Events

- **Webinar to present RBDCOV in COPEDICAT** : Thanks to the collaboration with WP3 leaded by Vall D'Hebron, we have been offered the opportunity to promote RBDCOV within the COPEDICAT research network, which includes over 170 primary care pediatricians and professionals from various hospitals in Catalonia. A webinar, led by our partner Pere Soler from Vall D'Hebron, was held on the 30th of June, presenting the project, the advances achieved, and the needs related to the recruitment of the clinical trial in children and adolescents.

Figure 35: Screenshot of Webinar to present RBDCOV in COPEDICAT

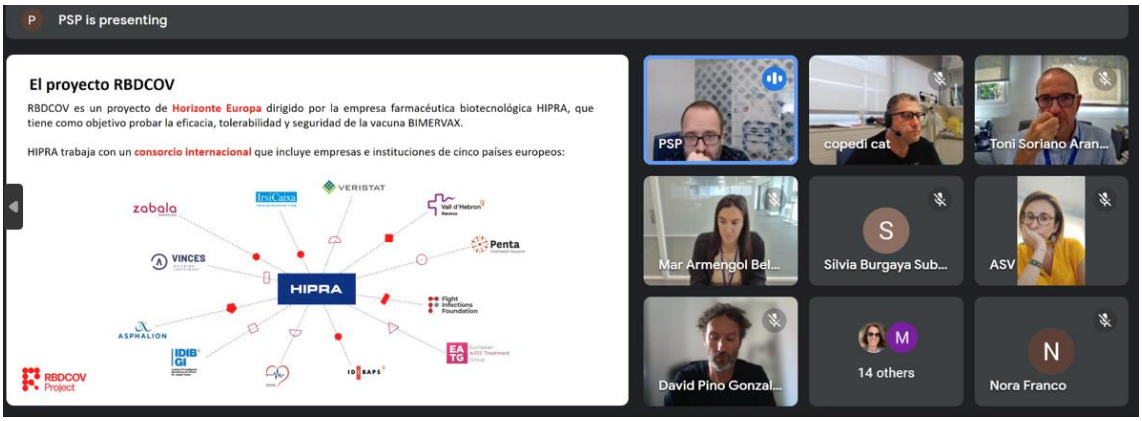


Figure 36: Screenshot of Webinar to present RBDCOV in COPEDICAT

- **Highhway to Health event :** On July 4th, ZABALA and HIPRA participated in the 'Highway to Health' event : a joint Cluster and Policy Event at the Representation of the State of Hesse to the EU in Brussels, Belgium, bringing together policymakers, health authorities, clinicians, and researchers to review the scope and benefits of COVID-19 actions and get prepared for future pandemics while strengthening our healthcare systems.
  In this event, Elia Torroella, coordinator of RBDCOV, was invited as a speaker and presented the project, highlighting its milestones and how we adapted to the pandemic situation. Thanks to our participation in this event, which is related to Task T8.4 (Networking with other projects and initiatives), we aimed to cluster with other health projects such as COVEND and Envision. Our goal was to present the project to key stakeholders, including researchers, policymakers, and EU health actors. See below the social media post promoting our participation and a brief report of our involvement in the event.

Figure 37: Highhway to Health event - Registration

- **REPORT - ENVISION – 04/07/23 HIGHWAY TO HEALTH – Visions in European HealthCare**

Bringing together researchers, clinicians, practitioners, policy- and decision-makers to shape the future of healthcare in Europe.
We had the opportunity to present RBDCOV among other health projects, and engage with various health stakeholders. Elia Torroella presented the Project, highlighting its milestones and how we adapted to the pandemic situation. We also could connect connect with health stakeholders during the event.

Some insights from the event:

- **How can we prepare for future pandemics?**
  - DG Research & Innovation emphasized the need for funding opportunities in pandemic preparedness and response research.
  - Establishment of coordination mechanisms between EU-funded research projects and initiatives for a synergistic response to infectious disease outbreaks.
  - Building research partnerships with EU member states to efficiently allocate investment towards a common objective.
  - Creation of a platform for open data sharing during and outside of pandemics.
  - Coordinating funding of research in pandemic preparedness with other global funders.
  - Supporting regulatory authorities to position the EU as a competitive center for innovative clinical research.

What have we learned to face future pandemics?

- The importance of pre-crisis planning and investment in research and innovation.
- The need for financing tools that can be rapidly mobilized.
- The significance of large-scale, multi-center, multinational clinical trials to generate robust evidence.
- Emphasizing the importance of dialogue and collaboration.
- **EU Commission's primary concern regarding future pandemics.**

Digitalization in European healthcare:
The European Commission highlighted the necessity of digitalization in the health sector.
The European Health Data Space challenge, aiming to enable better sharing of health data.
The challenge of diverse data processing systems in different hospitals and member states.
The involvement of patients in decision-making processes, with the Commission seeking input from researchers to foster collaboration.
The importance of involving technicians in policy-making decisions and promoting collaborative data analysis.

Society's ability to learn from each other:
Networking among healthcare professionals during the pandemic was exemplified by doctors reaching out to others for assistance.
DG Hera and its mission:
Strengthening Europe's ability to prevent, detect, and respond to health threats.
The Cohort Coordination Board brings together all EU-funded COVID-19 cohorts, ENC, and key agencies such as EMA and ECDC, along with partners. The board aims to ensure efficiency in cohort studies. Working groups focus on Long COVID and setting up observational studies during pandemic times.

Notable contacts from the event:
Patricia Urban, European Commission Policy Officer; Ulla Narhi, Director General of HERA; Andreas Holtel, European Research Executive Agency; Ms. Cathy Weynants – Chief Executive Officer, ESAIC; and Dr. Kai Zacharowski

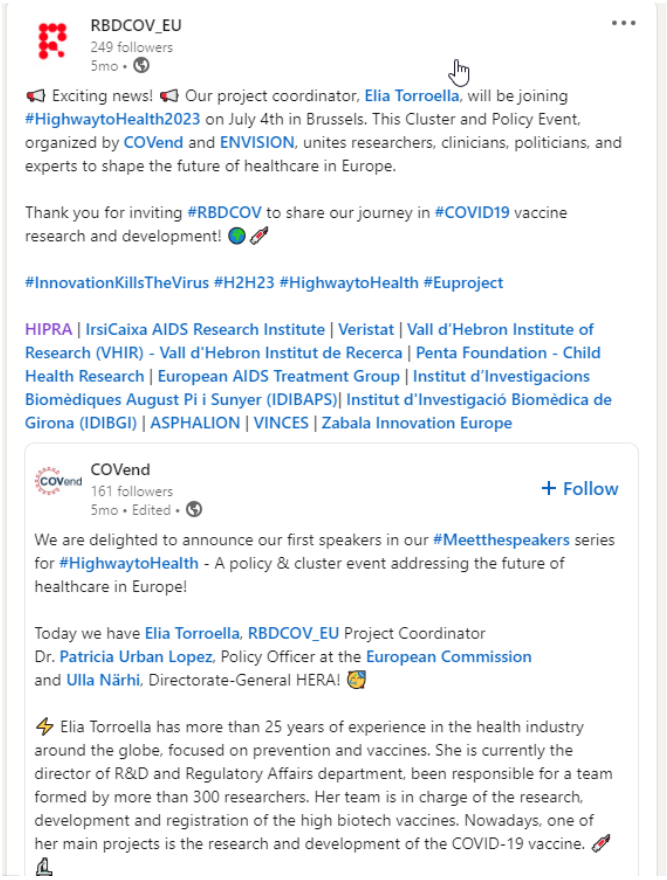


Figure 38: Promotion on Social Media of Highhway to Health event participation

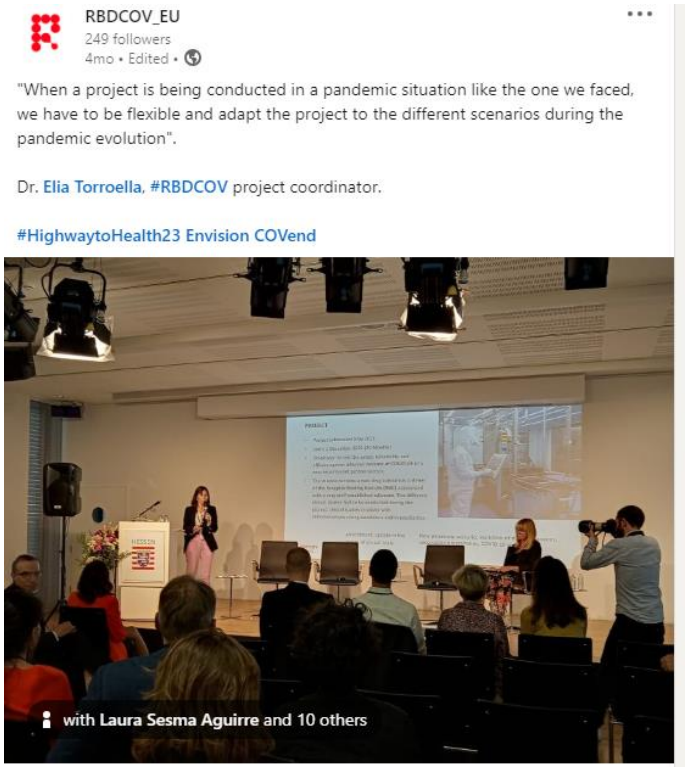


Figure 39: Promotion on Social Media of Highhway to Health event participation

- **Participation in WVC :** For the second consecutive year, we have participated in the World Vaccine Congress. In the first year, our partners ASPHALION and Zabala provided a QR code for the RBDCOV project, which was promoted. For this second edition, ASPHALION and HIPRA presented the latest results achieved in the first phase of the clinical trial in people with inmunocompromised conditions.

Figure 40: Promotion on social media of our presence in the WVC 2023

1.5. Media relations

The RBDCOV project has been promoted through media at the European and national levels. This action has been carried out through direct contact with the media through press releases (PRs). The press releases are first created by ZABALA and then revised by the coordinators and the project's Communication Team. Once approved, the PRs are shared with the RBDCOV partners' Communication Departments, who in turn, distribute it through their contacts. Additionally, besides Zabala, we have also promoted some press releases sent by HIPRA, providing information about milestones and advances in the BIMERVAX Vaccine—an information relevant to the RBDCOV project as well. All the PRs can be found on the website in English, Spanish and Catalan : Press releases - RBDCOV

Since the last report, the following PRs and Piece of News have been launched :

13th of October : Advance in the research of the HIPRA COVID-19 vaccine at the annual meeting of the RBDCOV Project

29th of May : The AEMPS authorizes clinical trial to study HIPRA's COVID-19 vaccine in adolescents aged 12 to 17

20th of January : The European RBDCOV project will study HIPRA's COVID-19 vaccine in children, adolescents and immunocompromised patient

Refer to the annex: Media clipping to view the impacts achieved.

1.6. Specific communication materials

Bringing the project and the clinical trial closer to citizens and addressing key audiences has been one of the objectives in creating specific communication materials that will be explained below.

Since the start of the RBDCOV project, we have developed graphic, visual, and multimedia materials, published on the website, distributed among the partners, and promoted on Social Media. These materials aim to present the technical aspects of vaccine development in a manner accessible to both the general public and a more specialized audience. For those unfamiliar with the subject, the following materials are available to aid in understanding the main differences among vaccines, the functioning of the BIMERVAX vaccine, and the significance and effectiveness of the RBDCOV project.

- **RBDCOV's project Video :** A video that summarizes the main purpose of the project, the partners involved, the different clinical trials to test the vaccine and the main benefits. The video explains, in less than 2 minutes, the main ideas of the project. Additionally, a piece of news to promote the video and explain in detail the advances of the project was published at the same time. This material has been used for events presentations and is available on the website, YouTube Channel and has been promoted on Social Media as well. Click on the image to view it.

Figure 41: RBDCOV Informative Video

- **Infographic :** explaining our vaccine in comparison with the other two existing ones.
  The material has been used both on the home page of the website, as well as in a news item dedicated solely to the infographic and its explanation for anyone who needs it, and it has also been used as communication support material at events.

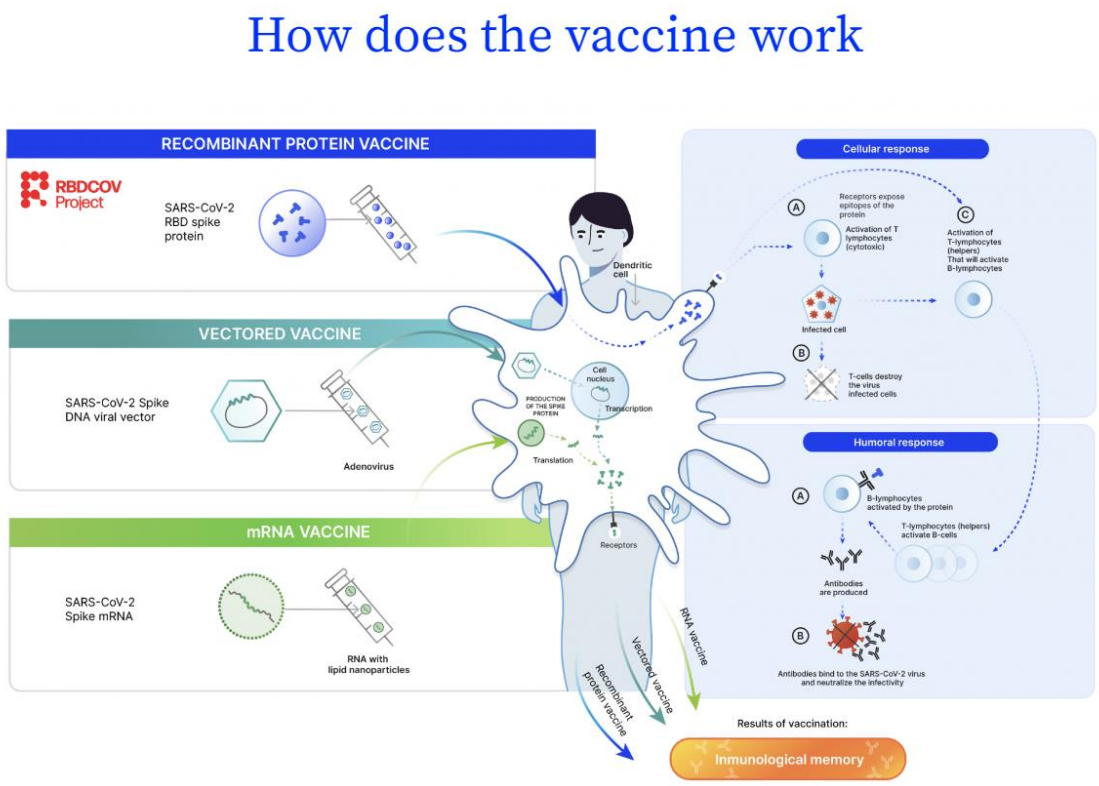


Figure 42: Explanatory infographic

- **RBDCOV Comic - A Vaccine Mission :** This material has been created with the aim of explaining how the BIMERVAX vaccine works, how our body prepares to protect against SARS-CoV-2 (the virus that causes COVID-19). he comic breaks down this complex process in a friendly and accessible manner, making it suitable for readers of all ages and backgrounds. It is available in English, Spanish, Catalan, and Turkish on the website and has also been adapted and distributed in the hospitals where the clinical trial is taking place.
  This material has been developed based on a concept by EATG, partner leading in community engagement. It has been reviewed by technical experts from HIPRA and approved by the HIPRA's ethics committee.

  The comic has been published on:
  - Website home page. News item.
  - Social media posts. Refer Social Media Campaigns in this document.
  - Hospitals

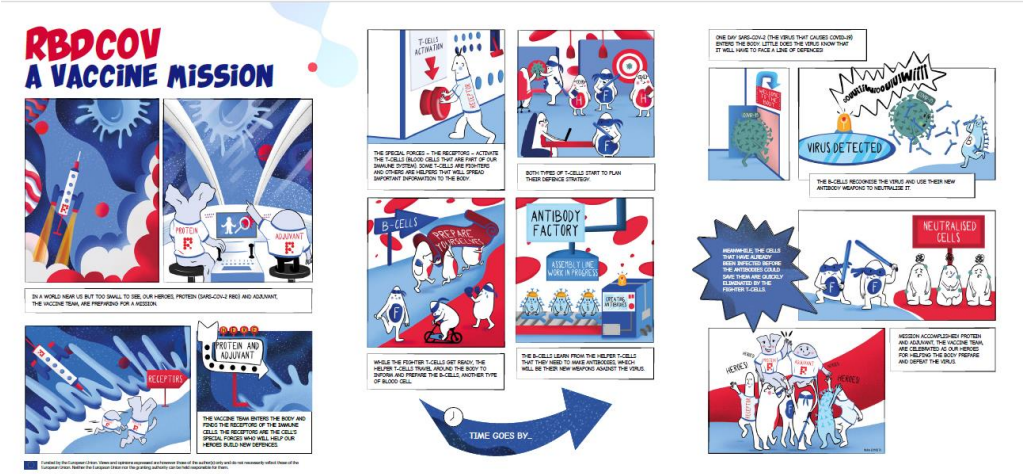


Figure 43: Comic - A vaccine mission - English

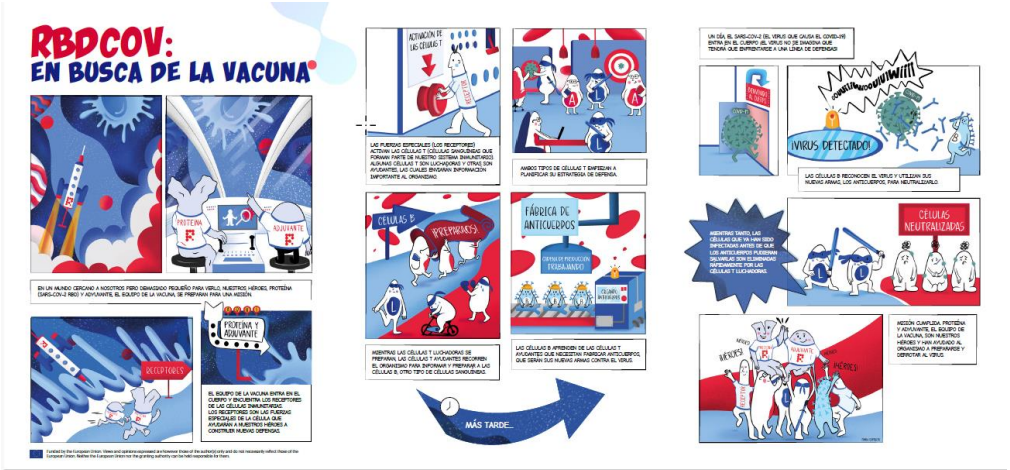


Figure 44: Comic - A vaccine mission for website - Spanish

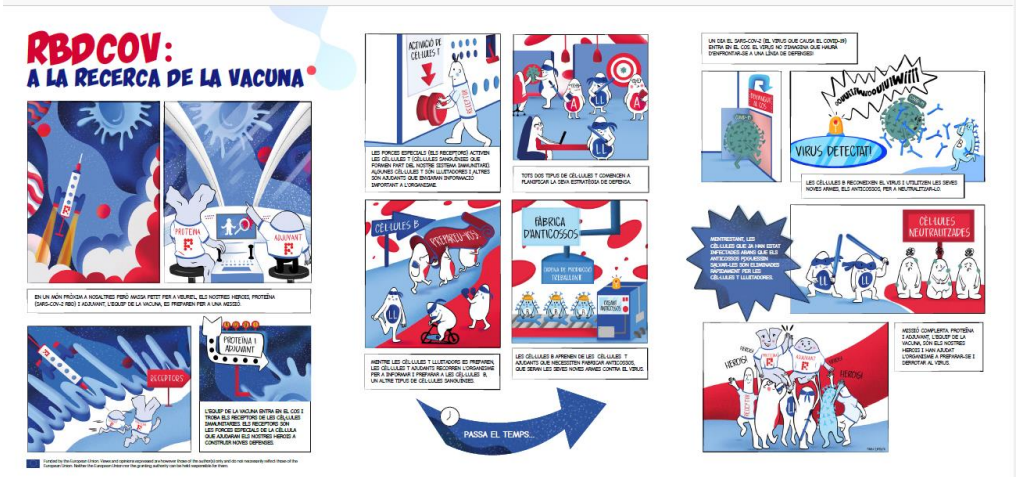


Figure 45: Comic - A vaccine mission for website - Catalan

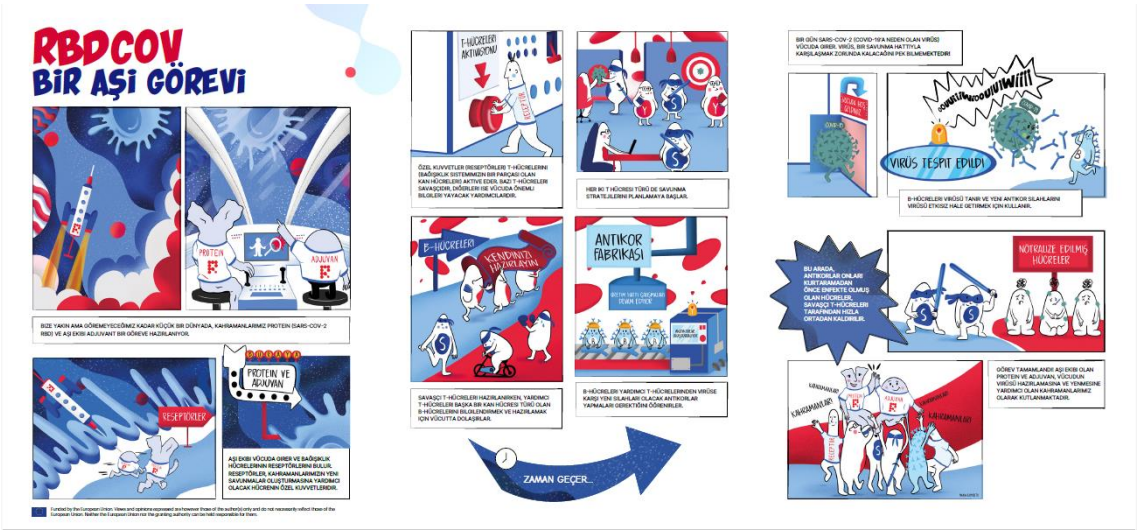


Figure 46: Comic - A vaccine mission for website - Turkish

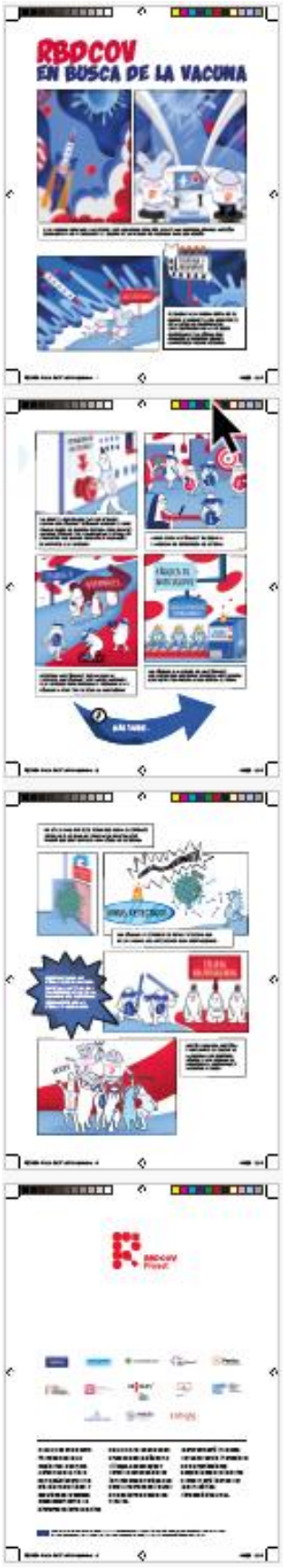


Figure 47: Comic - A vaccine mission for printing - Spanish

- **Poster for dissemination results.** Scientific dissemination poster templates have been created and distributed among the partners, facilitating the dissemination of project results, including preliminary results of the clinical trials, at scientific events and conferences.

Figure 48: RBDCOV Poster for dissemination results

- **Informative materials for the clinical trials :** The following materials compile all the relevant information related to the second clinical trial, focusing on adolescent patients aged 12-17 years. This material addresses the need for physical materials that can be distributed in health centers, allowing parents to consult and decide whether they want their children to participate in the clinical trial or not. It serves as an informative tool with a clear objective: recruitment. These informative materials have been prepared by Zabala and reviewed by the communication department and the Ethics Committee of HIPRA. The aim of these materials is to inform about the RBDCOV Project and the clinical trials. The materials have been prepared in English, Spanish, and Catalan for the website, as well as in printed versions such as leaflets and posters in Spanish and Catalan. These printed materials have been produced and distributed by HIPRA to the hospitals where the clinical trial is taking place.

Figure 49: Informative leaflet for printing: About RBDCOV and the clinical trial - Spanish

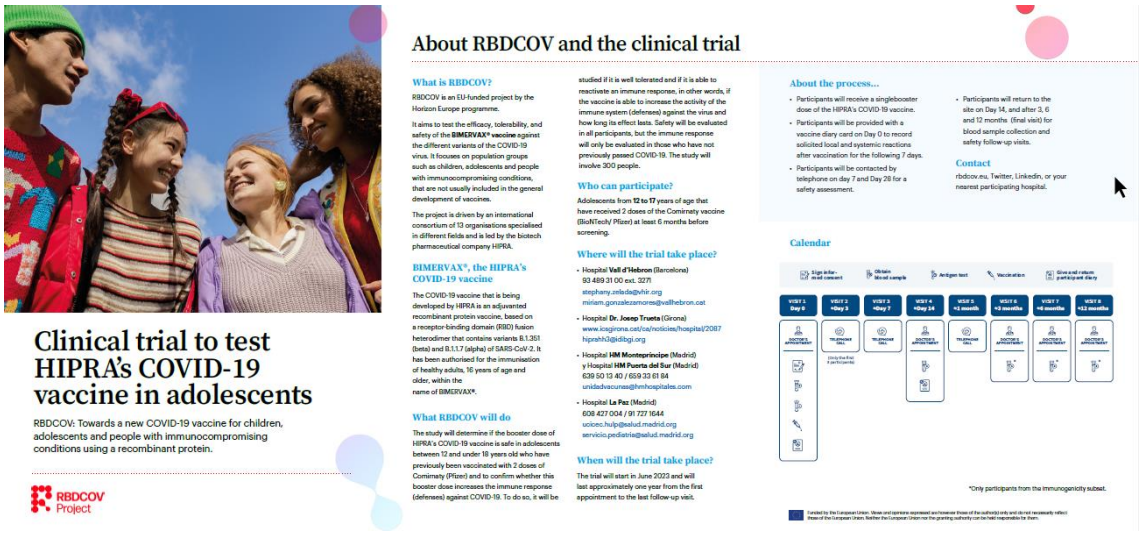


Figure 50: Informative leaflet: About RBDCOV and the clinical trial - English

Figure 52: Informative leaflet: About RBDCOV and the clinical trial - Spanish

Figure 53: Informative leaflet: About RBDCOV and the clinical trial - Catalan

RBDCOV Project

Ensayo clínico para probar la vacuna COVID-19 de HIPRA en adolescentes

Hacia una nueva vacuna contra la COVID-19 para niños/as, adolescentes y personas con condiciones inmunocomprometidas utilizando una proteína recombinante.

¿Qué es RBDCOV?

RBDCOV es un proyecto financiado por la UE mediante el programa Horizon Europe.

Tiene como objetivo probar la eficacia, tolerabilidad, y seguridad de la **vacuna BIMERVAX®** contra las diferentes variantes del virus del **COVID-19.**

Se enfoca en grupos de población como **niños/as, adolescentes** y personas con **condiciones inmunocomprometidas,** que generalmente no se incluyen en el desarrollo general de vacunas.

El proyecto está impulsado por un **consorcio internacional** de 13 organizaciones especializadas en diferentes campos y está liderado por la farmacéutica biotecnológica HIPRA.

BIMERVAX®, la vacuna de HIPRA contra el COVID-19

La vacuna contra el COVID-19 que HIPRA ha desarrollado es una vacuna de proteína recombinante adyuvantada, basada en un heterodímero de fusión con dominio de unión al receptor (RBD) que contiene las variantes B.1.351 (beta) y B.1.1.7 (alfa) del SARS -CoV-2. Ha sido autorizada para la inmunización de adultos sanos, a partir de 16 años, bajo el nombre de BIMERVAX®.

¿En qué consiste el ensayo clínico?

El estudio servirá para averiguar si la dosis de refuerzo de la vacuna contra la COVID-19 de HIPRA es segura en adolescentes de entre 12 y menos de 18 años que anteriormente han sido vacunados con 2 dosis de Comirnaty (Pfizer) y para confirmar si esta dosis de refuerzo aumenta la respuesta inmunitaria (las defensas) contra el COVID-19.

Para ello, se estudiará si es bien tolerada y si es capaz de reactivar una respuesta inmunitaria, es decir, si la vacuna es capaz de incrementar la actividad del sistema inmunitario (las defensas) frente al virus y cuánto dura su efecto. Se evaluará la seguridad en todos los participantes, pero la respuesta inmunitaria solo se evaluará en aquellos que no hayan pasado previamente la COVID-19. Participaran 300 personas.

¿Quién puede participar?

Adolescentes de **12 a 17 años** que hayan recibido 2 dosis de la vacuna Comirnaty (Pfizer) al menos 6 meses antes de la selección.

¿Dónde tendrá lugar el ensayo?

- Hospital **Vall d'Hebron** (Barcelona)
  93 489 31 00 ext. 3271
  stephany.zelada@vhir.org
  miriam.gonzalezamores@vallhebron.cat
- Hospital **Dr. Josep Trueta** (Girona)
  www.icsgirona.cat/ca/noticies/hospital/2087
  hiprahh3@idibgi.org
- Hospital **HM Montepríncipe** (Madrid) y Hospital **HM Puerta del Sur** (Madrid)
  639 50 13 40 / 659 33 61 84
  unidadvacunas@hmhospitales.com
- Hospital **La Paz** (Madrid)
  608 427 004 / 91 727 1644
  ucicec.hulp@salud.madrid.org
  servicio.pediatria@salud.madrid.org

¿Cuándo tendrá lugar el ensayo?

El ensayo comenzará en **junio de 2023** y durará hasta 12 meses desde la primera cita hasta la última visita de seguimiento.

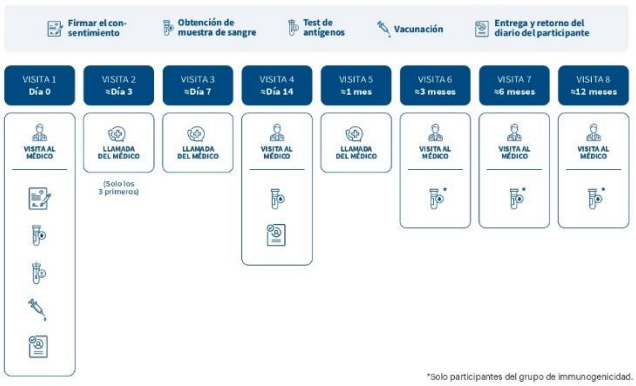
Acerca del proceso...

- Los participantes recibirán **una dosis** única de refuerzo de la vacuna contra el COVID-19 de HIPRA.
- A los participantes se les proporcionará un **diario** el Día 0 para registrar las reacciones locales y sistémicas solicitadas después de la vacunación y durante los siguientes 7 días.
- Los participantes serán contactados por **teléfono** el día 7 y el Día 28 para una evaluación de seguridad.
- Los participantes regresarán al lugar el Día 14 y después de 3, 6 y 12 meses **(visita final)** para la recolección de muestras de sangre y visitas de seguimiento de seguridad.

Contacto

rbdcov.eu, Twitter, Linkedin, o el hospital participante.

Calendario



*Solo participantes del grupo de immunogenicidad.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Figure 54: Informative poster A3: About RBDCOV and the clinical trial - Spanish

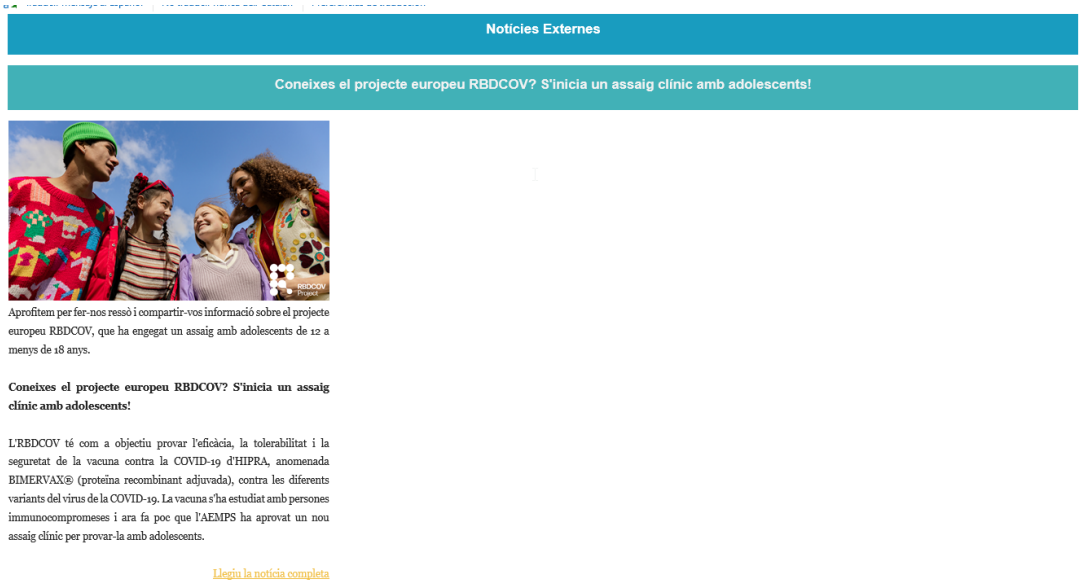
1.7. Written content

- **Specialised articles:** The aim of the specialized articles is to disseminate the knowledge of the experts participating in the RBDCOV project, explaining technical concepts and project phases. Promote awareness of the project. These articles engage users by explaining how vaccine trials work, addressing common questions about safety and regulations, and building trust. A detailed content plan has been prepared and coordinated with the partners who provided the content. This content has been adapted by Zabala, reviewed by EATG, and finally approved by HIPRA.

    - 1. Vaccine Clinical Trials: What is the process and how are our trials regulated? (ASPHALION) It has been published on July
    - 2. How vaccine clinical trials work? (VERISTAT) published in September
    - 3. All about personalized vaccines: what are they and what is their future? (IRSICAIXA) published in November

- **Presentation of RBDOCV in Escoles Sentinella :** The Schools Sentinel project is a network of educational centers throughout Catalonia that participate as co-researchers in areas such as mental health and infectious diseases in the school environment through participatory research. Established in 2020 in response to the need to describe and propose improvements regarding the impact of Covid-19 in school environments, the network has grown over the years, showcasing the benefits of collaboration between the educational and scientific communities. Consequently, we have identified them as an ideal channel for raising awareness about RBDCOV and promoting the clinical trial in children and adolescents within schools. This approach allows for direct contact and facilitates reaching the required number of participants for the clinical trial.

  As a primary initiative, information about the project has been incorporated into their newsletter, featuring the informative leaflet of the clinical trial and the comic, both of which resonate well with this audience.



Notícies Externes

Coneixes el projecte europeu RBDCOV? S'inicia un assaig clínic amb adolescents!

Aprofitem per fer-nos ressò i compartir-vos informació sobre el projecte europeu RBDCOV, que ha engegat un assaig amb adolescents de 12 a menys de 18 anys.

Coneixes el projecte europeu RBDCOV? S'inicia un assaig clínic amb adolescents!

L'RBDCOV té com a objectiu provar l'eficàcia, la tolerabilitat i la seguretat de la vacuna contra la COVID-19 d'HIPRA, anomenada BIMERVAX® (proteïna recombinant adjuvada), contra les diferents variants del virus de la COVID-19. La vacuna s'ha estudiat amb persones immunocompromeses i ara fa poc que l'AEMPS ha aprovat un nou assaig clínic per provar-la amb adolescents.

Llegiu la notícia completa

Figure 55: Newsletter Escoles Sentinella

Future Diss & Comm activities

1.8. 'RBDCOV Talks', a 10-episode podcast on vaccine clinical trials.

Production of a dedicated podcast, RBDCOV Talks, to bring knowledge about vaccine clinical trials to the general, non-specialist public in podcast format. This is a series of 10-episode interviews in which some of the project partners, specialists in the field, introduce and bring different concepts and relevant information about the world of clinical trials of vaccines.

The RBDCOV Podcast not only aims to generate awareness about RBDCOV and position the project among key stakeholders, creating appeal, building trust, and demonstrating transparency, but it also follows a user centered strategy focused on patients and the general population.

The podcast seeks to highlight how this trial benefits the population. Additionally, it aims to explain scientific terms that have been widely discussed during the pandemic and are common in scientific communities, but not well known to the general public, making them accessible to non specialized audiences interested in understanding how the vaccine works and the importance of clinical tr ials
in advancing medical research.

- Disclosure: To inform and disseminate on key project terms, achievements, vision and impact
- Approach/Humanisation: by making visible and giving a voice to the experts who are part of the project.
- **Positioning Tone:** Informative and approachable.

The next **target groups** have been defined :

- **Scientific community,**including European Research Infrastructures and other related projects.
- **Researchers, academia, universities and research organisations**
- **Civil society (not specialized)**
- **RBDCOV stakeholders Project** : other EU projects and third parties especially healthcare professionals and managers from the participating clinical centres, potential participants and community (children and patients with immunocompromising conditions).

With an approximate duration of 10 minutes, each episode deals with a specific topic and allows non-specialists to gain a better understanding of the subject, raise awareness of the importance of clinical research on vaccines and clear up any doubts in those people who consider taking part in clinical trials. Topics such as Drug Safety, procedures and phases of clinical trials, vaccine research against COVID-19, inclusivity criteria and personalised vaccines are some of the issues addressed in this podcast, which will be available to the public from the 29 November on three of the main podcast platforms : Spotify, Google Podcasts, Apple Podcasts.

To achieve greater impact, **the next promotion actions** have been planned :

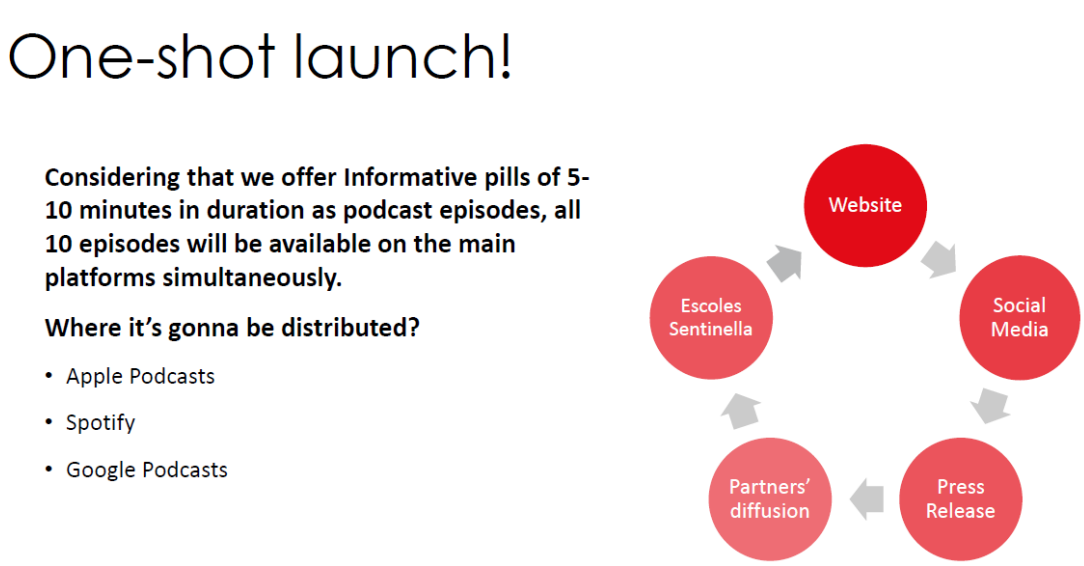


Figure 56: RBDCOV Talks - One-Shot Launch Strategy

- **Upcoming Press Release (Nov 2023): RBDCOV Talks podcast**

  In order to raise awareness of the 'RBDCOV Talks' initiative, the production of a dedicated podcast, a press release will be sent to the media in November 2023. In this way, it is hoped to broaden the dissemination of this initiative and to contact local media and audiences close to the different members of the consortium participating in this 10-episode interview series.

  It is expected that media outreach will help the RBDCOV project in its aim to innovate in new formats of medical-scientific dissemination, such as the podcast format, to bring the world of clinical trials and vaccines closer to a general and non-specialised audience.

- **RBDCOV Talks - Visual Identity**

  Following the branding guidelines, a visual identity for the podcast has been created. This identity will allow easy recognition of the podcast as a communication initiative under the project.

RBDCOV Talks

Figure 57: RBDCOV Talks - Visual Identity

- **Social Media Campaign**

Set of posts on LinkedIn and Twitter for the announcement of the podcast (1), promotion of the ten episodes (10), and one quote from each interviewee (10).

Strategy and purpose

The aim of such posts is to generate interest on different aspects of vaccine clinical trials that take place in the context of the RBDCOV project, to highlight the education and knowledge of some of the professionals successfully driving the project through its different phases, to acknowledge the suitability of the podcast as a format for disseminating and expanding knowledge of a medical-scientific nature.

Approach :

In line with the very nature of the two social networks, on LinkedIn we will take advantage of the relational potential and professional focus of this network, making specific mention to the professionals participating in the 'RBDCOV Talks' initiative, while on Twitter it will be more focused on the content in each of the episodes.

Media assets :

Cover image
Episodes preview
Quotes

See below some examples of the promotional visuals for Social Media :

Figure 58: Visual for RBDCOV Talks Promotion

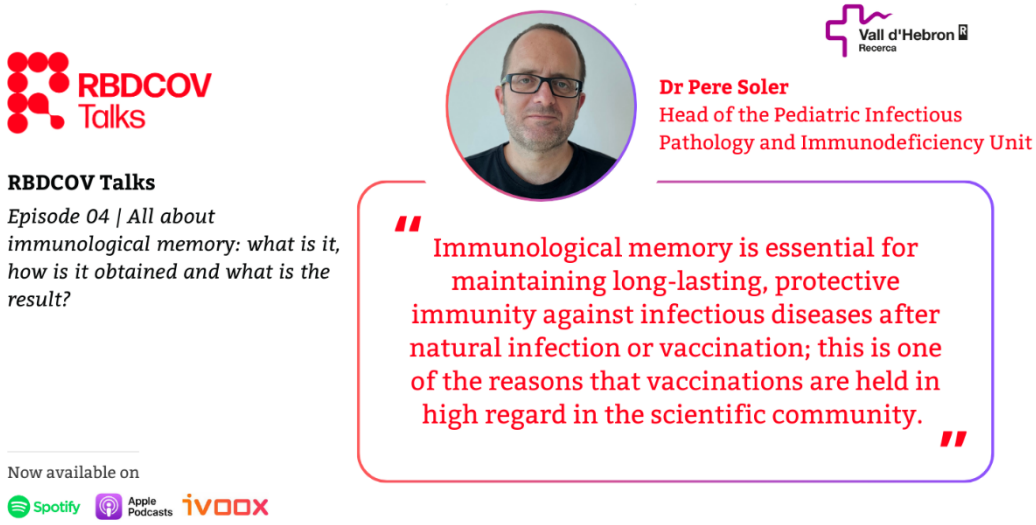


Figure 59: Visual for RBDCOV Talks Promotion - Example of one of the partners

1.9. Specialised Content

Due to the success of the expert articles, as indicated by the metrics in the News & Articles table for the time period from Feb 2022 to Nov 2023, we will continue with the specialized content plan for the remaining partners, publishing an article monthly. This action is not only valid for Communication: raising awareness about the RBDCOV project for a broader, non-specialized audience, but it is also valuable for the scientific community, because the authors are the researchers, scientists, and doctors directly involved in the project, those with technical expertise.

1.10. Publication of scientific papers

The following efforts will be oriented towards the dissemimation, promoting the publication of scientific papers. We are at a stage in the project in which we already have some results in WP4 and WP6. Currently, IRSICAIXA and VERISTAT are committed to preparing two papers, one each, for the next year. At least 2 papers (KPI. 2 papers) will be published under the project. The following instructions have been clearly explained to the partners in regular meetings, as well as in the Communication Group meeting.

- **The number of publications** will be defined in accordance with the results. Preference will be given to the generation of publications related with the project activities and results, which will be mainly submitted for publication in international scientific journals with as high impact and open as possible like Lancet, Nature, Journal of Virology, One Health Commission, or in the Open Research Europe publishing platform. Publications will follow the requirements of the Article 17 and Annex 5. All publications derived from the project will contain an acknowledgement of the EU Commission funding source.

- **The authorship** corresponds to the person who writes the paper, that is, the one who has obtained the results and publishes them. It is important that the author or authors upload the paper to Zenodo to promote Open Science and to showcase the scientific research work you are doing. or reasons of authorship and copyright, it must be the authors themselves who upload it to Zenodo. Once published, please let us know, and we will take care of uploading it to Funding&Tenders and publishing it on the RBDCOV website and social media.

1.11. Organization of the final event

Regarding the project's final event, a conference will be held in the European Parliament (Brussels, Belgium) at the end of the project to discuss the project outcomes and devise steps for moving forward to improve the RBDCOV vaccine.
In this final conference, the coordinator will do some introductory remarks, and a keynote speaker will kick off the conference. Then, the leaders of each WP will briefly present their results and findings. The attendees will be allowed to ask questions in the Questions and Answers session.

Finally, the coordinator will end the conference by outlining the next steps stemming from the RBDCOV project.

Regarding its organisation:

• The conference will be held between month 28 and month 30 on a date agreed by the partners.

• Zabala Innovation will prepare the necessary materials before the event, and all partners are responsible to send the invitations and ensure that the relevant stakeholders attend the event.

To promote the event, a press release detailing the results of the project will be finalised prior to the conference and distributed before the conference's start. The event will also be promoted in the European Commission's platform: Suggest an event | European Commission (europa.eu).

All the conference materials will be published online, in addition to their distribution to participants and partners.

Conclusion

As we can see in this detailed report, the implementation of the Dissemination & Communication strategy has been successful, positioning the project as a reference, as indicated by metrics, and achieving public recognition in the media. A wide range of communication actions has been executed, including the creation of different communication materials tailored to each targeted audience. Different channels, such as the use of Escoles Sentinella network, COPEDICAT have been explored with the aim of achieving the objectives established in the strategy, with a special focus on raising awareness and promoting recruitment and participation in clinical trials.

One clinical trial has already been completed, while another, focused on teens and adolescents, is currently in progress. Therefore, communication efforts have been primarily directed towards supporting WP4 in recruitment, and these efforts will persist until the required number of participants is attained.

Furthermore, the promotion of the project through participation in events, such as the Highway to Health event or the World Vaccine Congress, has been successfully achieved.

A continuous conversation has been maintained with partners, involving the proposal and dismissal of various actions. For example, the use of social media channels such as TikTok was initially considered but was ultimately discarded due to concerns about its perceived lack of trustworthiness in promoting the clinical trial.

In conclusion, we can demonstrate that the plan is a living document, incorporating new actions and channels not previously planned, seizing opportunities to utilize new channels proposed by partners.

For the last period of the project, we will continue with the main communication actions and the promotion of RBDCOV Talks as an innovative and potentially successful initiative. However, more effort will be allocated to Dissemination actions, including promoting the publication of scientific papers, participating in conferences, presenting results, and organizing the final event.

Annex 1. Press clipping

Organisation	News Title	Posted to website	Publishing date
IrsiCaixa	The European RBDCOV project will study HIPRA's COVID-19 vaccine in children, adolescents and immunocompromised patients	https://www.irsicaixa.es/en/european-rbdcov-project-will-study-hipras-covid-19-vaccine-children-adolescents-and	19/01/2022
Penta	HIPRA's COVID-19 vaccine trial in people with immunocompromising conditions launches in Turkey	HIPRA's COVID-19 vaccine trial in people with immunocompromising conditions launches in Turkey | Penta (penta-id.org)	19/01/2022
IDIBGI	El projecte europeu RBDCOV estudiarà la vacuna d'HIPRA contra la COVID-19 en infants, adolescents i pacients immunocompromesos	https://idibgi.org/projecte-europeu-vacuna-hipra-covid-19-infants-adolescents-immunocompromesos/	21/01/2022
EATG	RBDCOV: EATG represents community in a new project aiming to study COVID-19 vaccine	https://www.eatg.org/news/rbdcov-eatg-represents-community-in-a-new-project-aiming-to-study-covid-19-vaccine/	21/01/2022
VHIR	The European RBDCOV project will study HIPRA's COVID-19 vaccine in children, adolescents and immunocompromised patients	https://vhir.vallhebron.com/en/society/news/european-rbdcov-project-will-study-hipras-covid-19-vaccine-children-adolescents-and	24/01/2022
Penta	COVID-19 vaccines for children, adolescents and immunocompromised patients	COVID-19 vaccines for children, adolescents and immunocompromised patients | Penta (penta-id.org)	25/01/2022
Penta	European RBDCOV project to study HIPRA's COVID-19 vaccine in children	GB European RBDCOV project to study HIPRA's COVID-19	15/02/2022

	adolescents and immunocompromised patients	vaccine in children adolescents and immunocompromised patients | Penta (penta-id.org)	
IrsiCaixa	RBDCOV initiates the first Phase III clinical trial of HIPRA's COVID-19 vaccine in immunocompromised people	https://www.irsicaixa.es/en/rbdcov-initiates-first-phase-iii-clinical-trial-hipras-covid-19-vaccine-immunocompromised-people	17/05/2022
EATG	RBDCOV: the first clinical trial looking for a new COVID-19 vaccine is initiated	https://www.eatg.org/news/rbdcov-the-first-clinical-trial-looking-for-a-new-covid-19-vaccine-is-initiated/	17/05/2022
IDIBGI	RBDCOV inicia el primer assaig clínic Fase III de la vacuna d'HIPRA contra la Covid-19 amb persones immunocompromeses	https://idibgi.org/rbdcov-inicia-el-primer-assaig-clinic-fase-iii-de-la-vacuna-dhipra-contra-la-covid-19-amb-persones-immunocompromeses/	18/05/2022
Penta	RBDCOV initiates the first Phase III clinical trial of HIPRA's Covid-19 vaccine in immunocompromised people	RBDCOV initiates the first Phase III clinical trial of HIPRA's Covid-19 vaccine in immunocompromised people | Penta (penta-id.org)	18/05/2022
IDIBGI	RBDCOV initiates the first Phase III clinical trial of HIPRA's Covid-19 vaccine in immunocompromised people	http://biotech-spain.com/en/articles/rbdcov-initiates-the-first-phase-iii-clinical-trial-of-hipra-s-covid-19-vaccine-in-immunocompromised-people/	18/05/2022
IDIBGI	Empieza el ensayo clínico de la vacuna anticovid de Hipra en inmunodeprimidos	https://www.elperiodico.com/es/sociedad/20220518/ensayo-clinico-vacuna-hipra-covid-13673041	18/05/2022
IDIBGI	Assaig de la vacuna d'Hipra amb persones immunocompromeses	https://www.elpuntavui.cat/societat/article/14-salut/2141445-assaig-de-la-vacuna-d-hipra-amb-persones-immunocompromeses.html?utm_source=twitter&utm_medium=xarxes&utm_campaign=xarxes	18/05/2022

IDIBGI	L'Idibgi iniciarà dilluns l'assaig de la vacuna d'Hipra per a persones immunodeprimides	https://www.youtube.com/watch?v=XbWd8cO02nA	19/05/2022
IDIBGI	Primera reunió presencial del projecte europeu RBDCOV, que avalua la vacuna d'HIPRA en infants, adolescents i persones immunocompromeses	https://idibgi.org/primera-reunio-presencial-del-projecte-europeu-rbdcov-que-avalua-la-vacuna-dhipra-en-infants-adolescents-i-persones-immunocompromeses/	30/06/2022
EATG	EATG reports from RBDCOV's first General Assembly	https://www.eatg.org/news/eatg-reports-from-rbdcovs-first-general-assembly/	04/07/2022
EATG	RBDCOV: Working on an Inclusive COVID-19 Clinical Trial	https://www.eatg.org/news/rbdcov-working-on-an-inclusive-covid-19-clinical-trial/	20/10/2022
EATG	RBDCOV: COVID-19 vaccine trial in people with immunocompromising conditions has been launched in Turkey	https://www.eatg.org/news/rbdcov-covid-19-vaccine-trial-in-people-with-immunocompromising-conditions-has-been-launched-in-turkey/	17/01/2023
EATG	EATG reports from RBDCOV's second face-to-face meeting in Barcelona	https://www.eatg.org/news/eatg-reports-from-rbdcovs-second-face-to-face-meeting-in-barcelona/	01/02/2023
	La vacuna d'HIPRA contra la covid-19 rep l'autorització de l'Agència Europea del Medicament	https://www.lluita.org/actualitat/la-vacuna-dhipra-contra-la-covid-19-rep-lautoritzacio-de-lagencia-europea-del-medicament/	31/03/2023
	La vacuna de HIPRA contra la covid-19 recibe la autorización de la Agencia Europea del Medicamento	https://www.lluita.org/es/actualidad/la-vacuna-dhipra-contra-la-covid-19-rep-lautoritzacio-de-lagencia-europea-del-medicament/	31/03/2023
EATG	RBDCOV: HIPRA's booster vaccine against COVID-19, BIMERVAX®, receives EMA's positive opinion	https://www.eatg.org/news/rbdcov-hipras-booster-vaccine-against-covid-19-bimervax-receives-emas-positive-opinion/	04/04/2023
HIPRA	RDBCOV project. Features and clinical development of a protein vaccine against COVID-19.	https://sadip.org.ar/congreso/2023/img/programa.pdf	14/04/2023

EATG	RBDCOV: Face-to-face meeting with EATG's Community Advisory Panel	https://www.eatg.org/news/rbdcov-face-to-face-meeting-with-eatgs-community-advisory-panel/	02/05/2023
La Paz Univeristy Hospital	El Hospital La Paz busca voluntarios para estudiar la vacuna contra la COVID-19 de HIPRA en adolescentes	https://www.comunidad.madrid/hospital/lapaz/noticia/hospital-paz-busca-voluntarios-estudiar-vacuna-covid-19-hipra-adolescentes	31/05/2023
HM Hospitals	Los Hospitales Universitarios HM Montepríncipe y HM Puerta del Sur reclutan voluntarios para estudiar la vacuna de HIPRA contra la COVID-19 en adolescentes	https://www.hmhospitales.com/prensa/notas-de-prensa/reclutan-voluntarios-para-estudiar-la-vacuna-de-hipra	
IDIBAPS	HIPRA rep l'opinió positiva de l'Agència Europea del Medicament per la seva vacuna contra la COVID-19	https://www.clinicbarcelona.org/ca/noticies/hipra-rep-lopinio-positiva-de-lagencia-europea-del-medicament-per-la-seva-vacuna-contra-la-covid-19?from=research	30/03/2023
VHIR	Vall d'Hebron comença la cerca de voluntaris per estudiar la vacuna contra la COVID-19 d'HIPRA en adolescents	https://vhir.vallhebron.com/ca/societat/noticies/vall-dhebron-comenca-la-cerca-de-voluntaris-estudiar-la-vacuna-contra-la-covid-19-dhipra-en	08/06/2023
	Los médicos tranquilizan: la vacuna de Hipra sigue siendo efectiva pese a no estar adaptada a nuevas variantes de covid	https://www.elperiodico.com/es/sanidad/20230908/vacuna-hipra-covid-efectiva-omicron-nuevas-variantes-91775376	08/09/2023
VHIR	Els membres del projecte RBDCOV es reuneixen a Vall d'Hebron per avançar en el desenvolupament de la vacuna BIMERVAX	https://vhir.vallhebron.com/ca/societat/noticies/els-membres-del-projecte-rbdcov-es-reuneixen-vall-dhebron-avancar-en-el-desenvolupament-de-la-vacuna	11/10/2023
VHIR	Els membres del projecte RBDCOV es reuneixen a Vall d'Hebron per avançar en el desenvolupament de la vacuna BIMERVAX	https://vhir.vallhebron.com/en/society/news/rbdcov-project-members-meet-vall-dhebron-advance-development-bimervax-vaccine	11/10/2023

Vall d'Hebron	Els membres del projecte RBDCOV es reuneixen a Vall d'Hebron per avançar en el desenvolupament de la vacuna BIMERVAX	https://www.vallhebron.com/actualitat/noticies/els-membres-del-projecte-rbdcov-es-reuneixen-vall-dhebron-avancar-en-el-desenvolupament-de-la-vacuna-bimervax	11/10/2023
EATG	RBDCOV: HIPRA's booster vaccine against COVID-19, BIMERVAX®, receives EMA's positive opinion	https://www.eatg.org/news/rbdcov-hipras-booster-vaccine-against-covid-19-bimervax-receives-emas-positive-opinion/	01/04/2023
EATG	RBDCOV: Face-to-face meeting with EATG's Community Advisory Panel	https://www.eatg.org/news/rbdcov-face-to-face-meeting-with-eatgs-community-advisory-panel/	02/05/2023
EATG	RBDCOV: A Vaccine Mission – Explaining the journey towards COVID-19 protection with comics	https://www.eatg.org/news/rbdcov-a-vaccine-mission-explaining-the-journey-towards-covid-19-protection-with-comics/	07/08/2023
EATG	RBDCOV: A productive meeting for EATG's Community Advisory Panel	https://www.eatg.org/news/rbdcov-a-productive-meeting-for-eatgs-community-advisory-panel/	11/10/2023
EATG	RBDCOV: EATG reports from the latest face-to-face consortium meeting in Barcelona (October 2023)	https://www.eatg.org/news/rbdcov-eatg-reports-from-the-latest-face-to-face-consortium-meeting-in-barcelona-october-2023/	27/10/2023

Annex 2. RBDCOV Talks Scripts

Introduction

BROADCASTER:
Hello and a warm welcome to RBDCOV: Talks, a podcast proudly brought to you by the RBDCOV Project. In this series, we will embark together on a knowledge-packed journey to explore and discuss the world of vaccine clinical trials. For each episode, we will be joined by our dedicated team of experts, who have been at the forefront of this pioneering project. Together, we will understand how vaccine clinical trials

work and talk through interesting topics such as inclusion criteria in a vaccine clinical trial, personalised vaccines and what exactly immunological memory is.

So, fasten your seatbelts, dear listeners, as we delve into the heart of vaccines research and development. Stay tuned for RBDCOV: Talks.

RBDCOV is an European Project funded by the Horizon Europe programme that aims to test the efficacy, tolerability, and safety of BIMERVAX, the vaccine for COVID-19 developed by HIPRA.

Episode 1 - HIPRA: In 5 minutes, what is a recombinant protein vaccine?

BROADCASTER:

This is the first episode of our podcast series. In today's episode we will be discussing what a recombinant protein vaccine is with our special guest: Antonio Barreiro, HIPRA Human Health Project Leader Researcher, who has been closely working with his colleague Lluis Riera, HIPRA Medical Scientific Liason.

Thanks Antonio for joining us.

So, what exactly is a recombinant protein vaccine?

Antonio Barreiro: Before we start, let's back up a bit. All vaccines are based on administering a combination of substances to the person receiving the vaccine, to induce an immune system response that invokes protection against infection by the targeted pathogen, usually a virus or bacteria, so that the person does not contract the disease or has a reduced degree of disease.

The difference between vaccines directed against the same pathogen lies in the type of substances that are part of the compound [ABV1] used to induce the immune response in the vaccinated person. This includes the antigen, the key element that stimulates protection against a particular disease.

BROADCASTER: **Tell us more about the antigen, what is it?**

Antonio Barreiro: The antigen is the part of the pathogen capable of triggering the activation of the immune system of the vaccinated person. It can come from a variety of sources. For example, it can be the inactivated or attenuated pathogen itself. Alternatively, key parts of the pathogen can be used, usually proteins from its surface. The antigen provides the necessary information so that, once inoculated, the cells of the immune system induce an immune response that will protect the person in case of contact with the pathogen. The final goal is to prevent the development of the disease or significantly reduce its severity.

BROADCASTER: **What type of antigen is used in recombinant protein vaccines?**

Antonio Barreiro: In recombinant protein vaccines, the antigen used to induce the response of the immune system of the person receiving the vaccine are proteins of the pathogen, or part of these proteins, which are produced in the laboratory. In the case of the SARS-CoV-2 virus causing COVID-19, the main protein involved in the infection process is the Spike protein, located on the virus's surface. It is therefore the main candidate for vaccine design. Recombinant proteins are produced on a large scale by cells that are widely used in biotechnology for the manufacture of drugs of biological origin, and then purified to ensure their efficacy and safety. To get the cultivated cells to produce the desired protein, they are genetically modified to provide them with the information to produce the product of interest. What is administered with the vaccine is small amounts of this purified protein, which is usually accompanied by the adjuvant to enhance the immune system's response.

BROADCASTER: **Can recombinant protein vaccines transmit the disease for which they vaccinate?**

Antonio Barreiro: No. These vaccines are produced by cells that are completely free of the virus against which the vaccine is produced. In addition, they only contain one or part of the virus protein and have no ability to infect the cells of the person receiving the vaccine or to generate the symptoms associated with the infection.

BROADCASTER: **How many antigens can a recombinant vaccine carry?**

Antonio Barreiro: In some cases the vaccine may carry more than one associated antigen, especially when this is a fragment of a protein, so that the immune system of the person receiving the vaccine will be able to recognise more proteins of the pathogen, or more parts of the same protein. Proteins from different variants or strains of the same virus can also be combined, thus broadening the spectrum of protection and maximising the possibility of recognising and neutralizing it. .In some cases, proteins with more than one antigen in the same structure are synthesised, which can help to enhance the immune response against these antigens.

In both cases, these are referred to as multivalent vaccines. Specifically, vaccines containing 2 antigens are known as bivalent.

BROADCASTER: **What is the adjuvant?**

Antonio Barreiro: An adjuvant is a substance that boosts the immune response of a vaccine. There are different types of adjuvants and they are administered together with the recombinant protein of the vaccine, as it is usually not sufficient on its own to generate a strong immune system response to protect the person being vaccinated. The purpose of the adjuvant is to promote and enhance the activation of the immune system of the vaccinated person, allowing a stronger response [ABV1] and invoking better protection against the virus or pathogen. Also, the adjuvant can protect and stabilise the antigen during the vaccine storage, preserving its properties.

BROADCASTER: **Well, now we know what recombinant protein vaccines are, but how do they work?**

Antonio Barreiro: As mentioned previously, the aim of a recombinant protein vaccine, and vaccines in general, is to provide the person receiving the vaccine with protection against future infection by the pathogen to which the vaccine is addressed. To achieve this, the vaccine aims to generate an immune system response similar to the natural response which would occur if we were infected with the pathogen, but without developing the symptoms and disease that would normally be triggered by infection with the path**e**ogen. In this way, the immune system of the person being vaccinated acquires what is known as recall immunity against the pathogen. This consists of a variety of response mechanisms that will be activated when the person comes in contact with the pathogen, which will prevent us from becoming infected or, if we do become infected, the symptoms and disease developed by the pathogen will be much milder.

BROADCASTER: **Tell us more about what immunological memory is and how we get it.**

Antonio Barreiro: The immunological memory is a complex process in which different processes of the organism are involved simultaneously, but I will try to simplify it and make it understandable:

When a pathogen encounters our immune system for the first time, the first responder is innate immunity. In the same way, when the first dose of a vaccine is administered, this is also the first part of the immune system that is activated in response to the antigen and enhanced by the presence of the adjuvant.

Innate[ABV1] immunity is the first line of defence after the initial infection, it acts quickly, is non-specific and does not generate memory, but it is the basis for acquiring the sought-after immune memory that will protect us against the pathogen. At this early stage, specific cells involved in innate immunity capture and present the antigen, and at the same time they activate other cells of the immune system responsible

for an immediate response against the pathogen and inflammation (they are partly responsible for the local response at the site of vaccine administration). On the other hand, these antigen-presenting cells are responsible for activating the so-called adaptive immunity that is the key to the usefulness of a vaccine.

BROADCASTER: **What is adaptive immunity?**

Antonio Barreiro: Adaptive immunity is a slower response and generates a long-term defence, is specific and has memory. Once developed, when presented with a pathogen, it remembers whether it has seen it before and, if so, responds more quickly. In response to the activation of adaptive immunity, on the one hand, specific antibodies are generated against the antigen that help fight the pathogen and prevent infection and/or spread of the pathogen. On the other hand, adaptive immunity generates a group of cells that remain in the body and retain the information necessary to recognise and respond to the pathogen. And this group of cells forms the immunological memory that will allow our body to respond more quickly and effectively against the pathogen in the long term, preventing the infection or the harmful symptoms characteristic of the disease.

BROADCASTER: **So, what determines the usefulness of a recombinant protein vaccine?**

Antonio Barreiro: There are several aspects.

- One: it has to be specific for the pathogen for which it is designed, but at the same time with sufficient disparity to recognise small variations in the pathogen over time.
- Two: it has to induce an adaptive immune response with a good level of neutralising antibodies that recognise the pathogen and protect against infection or severe disease.
- Three: It is also important to generate sufficient immunological memory to ensure efficient long-term protection, so that frequent vaccinations are not necessary.

BROADCASTER:

And that's everything for today! We hope you enjoyed the beginning of this journey. Join us for our next episode with Antonio Barreiro from HIPRA.

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 2 - ASPHALION: What's Drug Safety? What is Drug Safety-level safety monitoring like in vaccine clinical trials?

BROADCASTER:
This is the second episode of our podcast series. In today's episode we will be discussing what's Drug Safety? and what is Drug Safety-level safety monitoring like in vaccine clinical trials? with our special guest: Helena Belinchon, Drug Safety Manager in ASPHALION.

Thanks Helena for joining us.

What is the objective of pharmacovigilance activities in a vaccine clinical trial?

Helena Belinchon: Drug Safety plays a critical role in vaccine studies and post-marketing surveillance to ensure the safety and effectiveness of vaccines. Before a vaccine is approved for widespread use, it goes through various phases of clinical trials. Drug Safety is essential during these trials to monitor and assess the safety profile of the vaccine. This includes the collection, analysis, and reporting of adverse events and adverse reactions associated with a vaccine.

Which kind of adverse events are collected in clinical trials with vaccines?

Helena Belinchon: Considering the nature of vaccines, the most expected reactions will be at the site of vaccine administration and are often mild to moderate in severity. These may include pain, redness, swelling, or tenderness at the site of injection. Other common reactions could be systemic reactions (ex: fever, headache…), involving symptoms or effects throughout the body. These reactions are generally mild and temporary. Although rare, vaccines can trigger allergic reactions, such as hives, difficulty breathing, and anaphylaxis.

However, during the conduct of Clinical trials, the Drug Safety department closely monitor and investigate serious adverse events to determine their cause and relationship to the vaccine. Serious adverse events are generally events that result in death, are life-threatening, require hospitalization or prolongation of existing hospitalization, result in persistent or significant disability or incapacity, or are otherwise deemed serious by the investigators or regulatory authorities. Other events of interest to followed are Adverse Events of Special Interest, which are specific adverse events that are of particular interest based on the vaccine under investigation and may include known risks or potential concerns. Vaccine trials pay particular attention to these events and collect data on them.

In addition, such unexpected, serious and related adverse events must be submitted to European and Local Authorities as per the applicable regulations.

How SAEs and AESIs are collected in Clinical trials?

Helena Belinchon: Participants plays an important role here; they are encouraged to report any AEs they experience between scheduled visits. Healthcare providers and trial investigators are then responsible for promptly evaluating these reports and documenting them according to the trial protocol. To collect data, investigators use standardized data collection forms to record all reported adverse events. These forms typically include details such as the event's description, onset date, severity, duration, outcome, and any actions taken in response. As a second step, investigators assess the relationship between the reported adverse events and the vaccine. The causality assessment helps to understand the vaccine's safety profile.

To ensure effective and continuous communication between the sites collecting adverse events and the Drug Safety department, a Safety Management Plan is signed between the all parties involved. This document describes the responsibilities of the Investigator, Sponsor, CRO and Safety department with regard to the management of the adverse events. This document will be aligned with the protocol to guarantee that serious adverse events, AESIS and other events are safely exchanged within the timeliness and describes the party responsible for submitting the unexpected, serious and related adverse events (SUSARs) to the concerned authorities.

And, where are all these adverse events reported and collected?

Helena Belinchon: In clinical trials, there will be two main databases, a clinical database and a safety database.

A clinical database in vaccine clinical trials is a comprehensive and organized collection of data related to the clinical aspects of the trial. It includes data on the study population, randomization, dosing schedules, immunization outcomes, and follow-up assessments., This will be primarily maintained by sites, Investigators, CRAs and Medical Monitors. A vaccine clinical trial safety database, on the other hand, focuses specifically on collecting, managing, and analysing data related to the safety profile of the vaccine. In addition, it is dedicated to documenting and monitoring adverse events, including both expected and unexpected events, that occur during the course of the trial. Whereas, the primary purpose of the safety database is to evaluate the safety of the vaccine under investigation. It tracks and assesses serious adverse events and adverse events of special interest to determine the relatedness to the vaccine and the impact on the study's safety outcomes. The Pharmacovigilance department bases their activities on the data collected in the safety database.

Both databases are critical components of vaccine clinical trials and are instrumental in ensuring the safety and efficacy of the vaccine being studied. The clinical database helps researchers evaluate how well the vaccine prevents the target disease, whereas the safety database allows for the monitoring and assessment of any potential adverse events or safety concerns associated with the vaccine. These databases play a crucial role in the overall assessment of the vaccine's eligibility for regulatory approval and public use.

Furthermore, all concerned parties should maintain close communication and both databases should be reconciled during the conduct of the clinical trials to ensure that the information exchanged is accurate and both databases are aligned and complete.

Which is the relationship between a Drug Safety department and the Regulatory Authorities?

Helena Belinchon: Drug Safety departments regularly submit safety reports to regulatory agencies, such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe. These reports provide detailed information on adverse events, including their frequency, severity, and causality assessment. Authorities review these reports to assess the safety profile of the product.

In addition, as mentioned previously, unexpected, serious and related adverse events that may occur are immediately submitted to the Authorities for prompt evaluation.

In summary, the relationship between a Drug Safety department and regulatory authorities is a symbiotic, as both parties collaborate to monitor and ensure the safety of pharmaceutical products, including vaccines. This collaboration is essential for maintaining public trust, ensuring regulatory compliance, and promptly addressing safety issues should they arise.

BROADCASTER:
Thank you so much, Helena. It has been a pleasure having you here. Also, a big thank you to all the people listening to us! And that's everything for today! We hope you enjoyed the beginning of this journey. Join us for our next episode with Montse Barceló from VERISTAT.

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 3 - VERISTAT: All about vaccine clinical trials: what are they and how do they work??

BROADCASTER:

This is the third episode of our podcast series. In today's episode, we will understand what vaccine clinical trials are and how they work. To do this, we have an exciting guest joining us: Montse Barceló from VERISTAT. She has been closely collaborating with colleagues Istvan Zatik, Rachel Abu Taleb and Hugo Bernard, members of the Medical Monitoring team who have played a significant role in creating the content for this episode.

Thanks Montse for joining us.

Let's get started with our first question: **what exactly are vaccine clinical trials and how do they work?**

Montse Barceló:When a new vaccine enters the phase of clinical development, a significant amount of investigations, experiments, and verifications have been performed and reviewed in detail. From there, three phases of development are required to demonstrate to the regulatory authorities the overall benefits of a vaccine far outweigh the risks:

- Phase 1: Establish the optimal dose for an efficient response with the least amount of side effects, and the characteristics of the Vaccine in a reduced number of participants. These are always healthy participants, due to the preventive nature of the product.

BROADCASTER:**… And how clinicians can identify an efficient response of the body in vaccine trials?**

MB: Well, of course, they will not infect the participants with the disease, that would not be ethical. They will check the organism's reactivity to the antigen. This antigen mimics an element of the virus itself. In practice, specific antibodies that recognize this antigen will be collected from the participant's blood and detected and quantified by immunoassays. It is also important to note that the technology used in this vaccine has been efficiently and safely used for decades in vaccines against Hepatitis B, Influenza, and Pertussis among others.

BROADCASTER:**How are we sure that the vaccine is efficient at this dose?**

MB: This is the object of the Phase 2 of the trial in this case: Determine the efficacy of the Vaccine based on the immune response, while guaranteeing participant's safety and integrity. In vaccine trials it involves participants that can be healthy or with stable conditions that would not interfere with their immune response. Their number is defined by a statistical analysis to obtain results with high confidence.

BROADCASTER:**And do you verify that the study is going along with the plan?**

MB: Usually, interim reports are requested, and provide preliminary but determinant information on the efficacy of the treatment. Finally, the Phase 3 allows to elaborate an extensive safety profile of the Vaccine in a less stringent population than in phase II, allowing, for example, some autoimmune diseases, as long as no immunosuppressive medications are taken. Additionally, Phase 3 further confirms the efficacy of the vaccine.

BROADCASTER:**What do you mean by "extensive safety profile"?**

MB: By monitoring the emergence of side effects it requires a high number of enrolled participants. Additionally, most vaccines are meant to be distributed to large populations, so it is important to have continuous monitoring of these safety events, for and even after marketing authorization. Recollecting safety data does not stop there, as we are now investigating special populations such as immunocompromised adults, and adolescents and children.

BROADCASTER:**In the context of the COVID-19 pandemic, what has been so special during the HIPRA trials?**

MB: HIPRA vaccine clinical trial stood out from the beginning. This was the very first human vaccine fully developed in Spain. A few months after the start of the pandemic, as some variants emerged and showed signs of viral immune evasion, HIPRA developed an antigen based on the two variants of most concern at the time. The choice of these mutations has proven to be smart and to date, they are still present in the variants of most concern. Already in August 2021 they were able to launch a phase I/II trial, then in November phase II, and in February 2022 phase III. This was an unprecedented situation given the emergency at the time.

BROACASTER: **How did you manage to accomplish such tight timelines?**
MB: We delivered all the essential documents and the data recording system in record time. For instance, while data recording systems are built and ready to go in 10 to 12 weeks, they were done in between 2 to 4 weeks for these trials. Then hundreds and thousands of participants were recruited in just a few weeks. Absolutely incredible! All this was done without compromising the quality of the data being collected or affecting the safety of the participants.

BROADCASTER: **The EMA, the European Medicine Agency, given the promising results of BIMERVAX, decided in May 2022 to start a rolling review of the vaccine. What is it, and how did it affect your work?**

MB: This rolling review is a regulatory tool that the EMA used in the context of the pandemic to speed up the assessment of the vaccine. It enables the continuous communication and the delivery of multiple reports until EMA's full satisfaction, but it involves an increased workload of expedited reports. In this context, it required many interim reports to be delivered to the authorities.
This was an important challenge: we needed to set up a worldwide coordination between operative departments, with special consideration to the deliverables. An extended team spread over three continents, with a strong record of experience in clinical trials, was gathered to absorb the periods of high work demand. For instance, the first interim report of the phase II study was delivered on time thanks to the dedication of more than 40 people and more than 28 consecutive hours.

BROADCASTER**: Were there other challenges?**

MB: Clinical research on COVID-19 vaccines at this time was on an ever-changing landscape, due to changes in the risk levels, the priorities of the society, and the overall knowledge of the disease. The objectives set by the protocol had to be adapted, as well as the criteria for safety surveillance, pushing everyone to be responsive and find innovative solutions. For instance, as severe COVID-19 cases drastically reduced, this parameter needed to be adapted.

BROADCASTER: **In summary, what has been your experience with the HIPRA trials?**
MB: From our point of view, HIPRA trials were an incredible and unique experience where one could witness the lifecycle of a trial just like a timelapse video. It could be said that this frantic frame rate could harm the quality and the safety of the clinical trial, but this was not the case here. For this, an open mindset, flexible and modular monitoring tools, additional surveillance, and continuous communication with authorities were the safeguards of the success of this project.

BROADCASTER: **Thank you very much. Any closing remarks?**
MB: Vaccines have saved countless lives for centuries now since the first one was created, and they continue to be one of the most effective public health measures to ensure the health of a population. From Veristat's side, it has been an honour to be involved in such an important achievement this has brought to the world. This is one more proof of how capable we all are of overcoming these drastic global events and shows how resilient we can all be.

BROADCASTER:
Thank you so much, Montse. It has been a pleasure having you here. Also, a big thank you to all the people listening to us! And that's everything for today! We hope you enjoyed the beginning of this journey. Join us for our next episode with Dr. Pere Soler from Vall d'Hebron Barcelona Hospital.

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 4 - VALL DHEBRON: All about immunological memory: what is it, how is it obtained and what is the result?

BROADCASTER: This is the fourth episode of our podcast series. In today's episode we will find out everything about immunological memory thanks to our great guest: Dr.Pere Soler from Vall d'Hebron University Hospital and Vall d'Hebron Research Institute. Thanks Dr. Pere Soler for joining us.

So, let's delve into this interesting topic. **What exactly is immunological memory?**

Dr.Pere Soler: To understand the immunological memory we need first to understand the immune System. The immune System is a vast and complex interconnected network of many organs, cells and proteins that work together to protect the body from illness. It is essential to fight against infections such as COVID-19.
There are 2 types of immune System: Innate immunity and the adaptive inmmunity or also known as acquired. The innate immunity is the one that you inherit and it starts to work when you are born. It's related with the physical barriers on and in the body. The adaptive immunity is the one that 'learns things'. For example. When your immune System is exposed to a new germ for the first time, it responds by trying to fight it off – which means you may become sick. But afterwards, the immune cells will remember the invader and will be ready to fight against this faster and more eficient than the first time.
So Immunologic memory is another important characteristic of adaptive immunity. It means that the immune system can remember the antigens that previously activated it and launch a more intense immune reaction when encountering the same antigen a second time.

BROADCASTER: **How is it obtained?**

Dr.Pere Soler: Upon entry to the host's body, a pathogen as SARS-CoV-2 is recognized as non-self by antigen-presenting cells, a group of immune cells that detect and engulf pathogens. Later, APCs display antigens that correspond to the encountered pathogen on their surfaces and present them to T cells, causing subsequent T cell activation, differentiation, and expansion. During the first encounter with a pathogen, T cells differentiate to effector T cells, which can mount an efficient and immediate immune response against the pathogen. Some effector T cells (cytotoxic T cells) directly kill infected cells, while others, known as helper T cells, help immune cells mount a response, including stimulating B cells to secrete antibodies against pathogens and generate memory B cells. Upon pathogen clearance, most of these differentiated effectors T cells die, while the surviving cells become long-lived memory T cells. These memory T and B cells are the clue for immunological memory.

BROADCASTER**: What is the result?**

Dr.Pere Soler: Immunological memory is essential for maintaining long-lasting, protective immunity against infectious diseases after natural infection or vaccination; this is one of the reasons that vaccinations are held in high regard in the scientific community. The development of vaccines has been one of the major achievements in public health in human beings and the prevention of severe forms of COVID-19 during the pandemic saving millions of lives is a great of example of this beneficial effect.

BROADCASTER:
Thank you so much, Dr Pere Soler! And that's everything for today! We hope you enjoyed this episode. Join us for our next discussion with Dr Pablo Rojo from PENTA.

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 5 - PENTA: Why have paediatric and adolescent participants been included in this trial?

BROADCASTER: This is the fifth episode of our podcast series, where we will be talking about clinical trials with children and adolescents. Let's welcome paediatric infectious diseases specialist, Dr Pablo Rojo, from Hospital 12 de Octubre in Madrid & PENTA. For this episode, he has collaborated closely with his colleagues Musakanya Ching'andu and Riccardo Melillo Verri.

Welcome Pablo and thanks for joining us!

Pablo, why are children and adolescents involved in the RBDCOV clinical trial?

Pablo Rojo: The simple answer is because it is crucial. The COVID-19 pandemic has shown us that vaccines play a crucial role in safeguarding public health, and it is essential to ensure that everyone, including our younger population, is adequately protected. The RDBCOV project aims to gather crucial data on the HIPRA vaccine's performance in children and adolescents and by including this age group, we can better understand the vaccine's potential impact on younger populations.

As you mentioned before, I am a paediatric infectious diseases specialist, but I am also a member of the Penta ID Network. Penta is an international, independent scientific network devoted to advancing research on improving the prevention, diagnosis, and treatment of infectious diseases in children and has for more than 30 years conducted paediatric clinical trials across the globe and brings that experience and extensive paediatric network into the RBDCOV project.

BROADCASTER: So, let's unravel this topic of involving children and adolescents in the RBDCOV trial a little bit.

Pablo Rojo: The matter of including children and adolescents in clinical trials is incredibly important, and it is a topic that I am passionate about, because I believe that we cannot confidently say that we have developed an effective vaccine if we have not ensured that all those who are at risk of acquiring the disease are also included in the trials that led to the development of the vaccine. And often times, children and adolescents are only included in these trials much later on, after an adult vaccine has been developed. Sometimes they aren't included at all.

Children and adolescents make up a significant proportion of the population and we can't simply ignore them when developing medication and vaccines, especially for emerging infectious diseases like COVID-19 which has and continues to evolve and pull us further and further into uncharted waters.

BROADCASTER: So it is impossible to downplay the importance of the RDBCOV project, since it has been set up to test the efficacy and safety of the vaccine against the variants of COVID-19 through two new clinical trials.

Pablo Rojo: Absolutely and the trials rightfully involve children and adolescents because children and adolescents have different physiological and immunological characteristics from adults, we can't just assume that a vaccine that is safe for adults necessarily means it is safe for children and adolescents. Their immune systems are still developing, and they may respond differently to vaccines. Also, the dosage that works well for adults may not be appropriate for children.

BROADCASTER: So adult formulations, although safe and effective in adults, aren't necessarily the best options for children and adolescents.

Pablo Rojo: That's right, and without specific clinical trials involving this age group, we can't be certain of the safety and efficacy of these medications and vaccines in children and adolescents. It's essential to gather evidence-based data to make informed decisions about vaccine use in each age group.

Also, the adult trial participants as well as the general public should always be informed of the clinical study findings. However, there is currently little in the way of practical advice and practice-specific literature regarding how to share results with paediatric trial participants and the larger paediatric community in an age-appropriate manner. Nevertheless, we should focus on this issue as well after the publication of the study results.

So, by conducting these clinical trials, which include children and adolescents we are ensuring that they too receive the best protection against infectious diseases. The RBDCOV clinical trial is including children and adolescents not just as a scientific necessity; but also because it is an ethical responsibility. By including them in the trial, we prioritize their health and well-being and pave the way for a healthier

future. If we want to achieve widespread immunity and control infectious diseases effectively, we must continue our commitment to evidence-based research that includes everyone, the old and the young.

Thank you so much, Dr. Pablo Rojo! And that's everything for today! We hope you enjoyed this episode. Join us for our next discussion with Juanfran Cabrera and Arda Karapinar from the European AIDS Treatment Group.

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 6 - EATG: Why should people living with HIV and other immunocompromising conditions be included in clinical trials similar to the RBDCOV trial?

BROADCASTER:

This is our sixth episode of our podcast series. In today's episode we will be talking about the inclusion of people living with immunocompromising conditions in clinical trials similar to the RBDCOV trial. To help us explore this topic, we have the privilege of welcoming Juanfran Cabrera and Arda Karapinar, Community Advisory Panel members from the European AIDS Treatment Group, our RBDCOV partner leading on community engagement and coordinating. The CAP is coordinated by EATG and brings together15 community experts living with different health conditions, who bring the community perspective to all aspects of the project.

For the creation of this episode, they have collaborated with two other CAP Members, Brian West and Mona Sundnes.

Welcome Juanfran and Arda and thanks for joining us today

Why should people living with HIV and other immunocompromising conditions be included in clinical trials similar to the RBDCOV trial?

Juanfran: Clinical trials are currently still not inclusive or representative of the people that will benefit from the treatment or intervention. People living with certain health conditions such as HIV and other immunocompromising conditions, have often been excluded based on their health condition alone. Also, children, adolescents, cisgender women and trans people are excluded from clinical trials, even though they can be the primary target as well for the drug or vaccine being developed. We need to ensure their participation in order to fully understand the drug's efficacy and safety.

This historical and systematic exclusion from clinical research happens because often pharmaceutical companies want to get a drug to the market quickly and receive the marketing authorisation from the European Medicines Agency by submitting "clean data" from the "healthy population". But even the notion of the "healthy population" is something that needs to be questioned. For example, we all know that HIV is now a chronic and manageable condition when receiving effective treatment. And, as people with HIV are living longer lives, non-HIV related health conditions are often and disproportionately experienced and this can have an impact on overall health and wellbeing.

Arda: This exclusionary process also does not give a realistic appraisal of how trial drugs will perform in real life situations. In the real world many of the people who are excluded will be the first to want or need access to the new drugs or vaccine. It is imperative that information on how these drugs work in key populations is collected in the clinical trial setting first. This could also help in the post approval phase,

when national authorities assess the economic implications before approving a drug or vaccine at a national level.

BROADCASTER: ***Was this also the case for COVID-19 vaccine trials?***

Arda: And the COVID-19 pandemic was a good example. Studies showed that people living with HIV have an increased risk of severe COVID-19 illness and an increased risk of dying from COVID-19. But initially, people living with HIV were not included in key COVID-19 vaccine studies even though the reality is that people living with HIV and other immunocompromising conditions were always going to be the target group most in need of the vaccines. It was then shown that COVID-19 vaccines were indeed safe and effective in people living with HIV, but with weaker, and shorter responses to vaccination.

So, by including people with immunocompromising conditions in the clinical trials of new drugs or vaccines, once the drug or vaccine is marketed, the data will be available to know how efficient and safe it is for a wider group of people who will use it. We will know if there are any possible drug-drug interactions and how dosages may or may not need to be adjusted, for example. Including people with immunocompromising conditions can ensure that real trials exist for the wider population. This will improve the generalisability of the results of clinical trials and the distribution of the benefits of the research will be more equal.

BROADCASTER: ***And what about the RBDCOV trials?***

Arda: The RBDCOV trials do include people with immunocompromising conditions, such as: HIV (with a CD4 count less than 400), chronic autoimmune disease, primary antibody deficiency disorders, chronic kidney disease (on dialysis), and people who have received a kidney transplant.

And this is crucial, as these specific groups are more likely to receive regular COVID vaccinations, while the population without health conditions may only receive the vaccine once a year or not at all, similar to flu vaccines. As these specific groups may require multiple doses before achieving optimal effectiveness, failing to incorporate these groups in the RBDCOV trials, and more generally in clinical trials, would in fact result in incomplete data.

Juanfran: And this was a first step to address the systematic change that we need in current research thinking and practice and improve access and availability of healthcare for a more holistic population. Involving people living with immunocompromising conditions from the earliest stages of clinical research is an opportunity to help build trust between communities, researchers and health professionals. And this can contribute to a global effort to empower community members, as well as to an overall improvement in the research and development process, enabling real research for a real population.

BROADCASTER:

Thank you Juanfran and Arda for this interesting discussion! And that's everything for today! We hope you enjoyed this episode. Join us for our next discussion with Julia Garcia-Prado from IRSICAIXA.

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 7 - IRSICAIXA: All about personalised vaccines: what are they and what is their future?

BROADCASTER: This is the seventh episode of our podcast series and today we will be discussing what personalised vaccines are and what their future might be. Let's welcome Julia Garcia-Prado from IRSICAIXA.

Welcome Julia and thanks for joining us!

BROADCASTER: ***Let's start with our first question, what do we mean with personalised vaccines?***

Julia Garcia-Prado: Science is moving away from the "one-size-fits-all" approach more and more and closer to **personalised medicine**. The medical strategies adopted so far allow us to prevent, diagnose and cure many diseases and greatly improve our quality of life. However, offering a personalised strategy that accounts for individual particularities could increase the impact of clinical success in medicine.

Much of the progress towards personalised medicine is enabled by **omics**. Omics constitute a field of research that has blended biomedical research, technology and bioinformatics. Omics allow us to study and integrate data from hundreds of genes, proteins or any molecule of interest in people at a time, and at an astonishing speed, we can detect individual particularities in response to treatments and vaccines.

In the case of **infectious diseases**, we are also looking for some approaches to have more personalised strategies for treatment, diagnosis or prevention. One of the ways to do this is through the personalisation of **vaccines**.

When we get vaccinated, we generate high levels of protective antibodies, called neutralising antibodies, and a strong cellular response against the virus. This happens ideally but is not always the case. The literature allows us to confirm that not everyone responds in the same way to a vaccine. There are a lot of factors that determine how we are going to respond, both intrinsic and environmental. Some people may be at a higher risk of severe disease or complications from contracting a virus, such as those with compromised immune systems -for example people living with HIV or primary immunodeficiencies, or people who have had a kidney transplant. For these people reduced vaccine response can hinder protection against certain pathogens, like a virus or bacteria that can cause a disease).

BROADCASTER: **How can vaccines be personalised?**

The term "personalised vaccines", refers to 'targeting' vaccine antigens (which are the parts of a pathogen that stimulate a response from the immune system.) towards an optimised outcome. Personalised vaccines maximise the immune response and minimise the risk of either vaccine failure or vaccine adverse reactions and side effects in people at risk of serious disease or complications.

BROADCASTER: **How can we achieve these objectives?**

The first step is understanding **how the population's immune system responds to vaccines.** To this end, at IrsiCaixa we have put a lot of effort into designing techniques to analyse the immune response in several ways and thus be able to determine how each person responds to a vaccine. Specifically, we study parameters such as the levels of antibodies with protective capacity against the virus and the response of the immune cells responsible for eliminating the virus and generating the immunological memory. With these factors, we can estimate the protection people acquire through vaccination and look for factors that affect the level of immune response. With this information, we want to identify the people who generate a lower or even no immune response, and find the best strategy to optimise their vaccine response.

In the case of COVID-19, we have studied the response of different groups, such as the elderly, people living with different health conditions, and people who have just received an organ transplant, among many others. In the case of the RBDCOV project, we study the response of children and immunocompromised people to the COVID-19 vaccine. Our group also studies other vaccines, such as for HIV, cancer, and hepatitis, among others.

With all this information, we want to quantify and predict what the immune responses or side effects of vaccines will be like for each individual. This knowledge will accelerate the development of personalised vaccines that maximise the impact on each individual..

BROADCASTER: **And how does this affect people, concretely?** Personalized vaccines can revolutionise medicine by providing vaccines tailored to the individual's unique biological characteristics. They are particularly promising in the field of cancer, where tumour characteristics can vary significantly between individuals, making a one-size-fits-all approach less effective. Vaccines for cancer are immunotherapy in which a vaccine is used to stimulate the patient's immune system to attack tumour cells. Scientists are able to work to find therapies that attack the specific tumour, increasing its effectiveness. At IrsiCaixa, for example, we are working on the design of a vaccine platform for pancreatic cancer.

In summary, by studying the immune response of many people from different target groups we can group different profiles of immune responses to vaccines and adapt them to their specific needs. How do we adapt them? We can modify the vaccine components, the concentration of these components, the vaccination schedule and other aspects. All of these modifications would allow us to optimise each group's responses and ensure their protection against several diseases.

BROADCASTER:

Thank you once again Julia! And that's everything for today! We hope you enjoyed this episode and that you join us for our next discussion with Mete Tan from METPHARM.

And, as always, if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!

Episode 8 - METPHARM: Where are we with COVID-19 and what does the future hold?

BROADCASTER:

This is the eighth episode of our podcast series and today we will try to understand where we are with COVID-19 and what the future holds. For today's discussion, we have the privilege of welcoming Mete Tan, partner in EU RBDCOV project and responsible for the RBDCOV clinical trial in Turkey.

So Mete, thank you for joining us here today, on the 9th of October of 2023. Considering how changing the COVID situation is, I wondered if you might share your thoughts on what the current landscape is regarding the project, and, more generally Covid vaccination?

Mete Tan: The number of reported COVID-19 cases has decreased significantly compared to previous years. This overarching decline can be attributed to the widespread use of national vaccination campaigns, improvement in public health measures, and acquired natural immunity through prior infections. During last 6-7 months there has been considerable decline in patient admissions to hospitals and decline in Covid test numbers due to decrease in severity of Covid-19 infection. Some countries are no longer monitoring cases at national level . It is estimated by the World Health Organization -the WHO- that by the end of September 2023 total Vaccine doses administered is 173 per 100 population in global and it is 185 in European countries. Persons vaccinated with a complete primary series is 66 per 100 population in global and it is 65 in Europe. Persons vaccinated with at least one booster or additional dose is 32 per 100 population in global and 35 in Europe.

The SARS Covid-19 virus has not been eradicated, vigilance remains essential,and the impact of Covid-19 is far from over. Recently Pirola (BA 2/86) is identified by WHO as a new variant of concern with a high

number of mutations on the spike protein of the virus, potentially evading immunity. The emergence of such new variants is common, although so far we have seen these emerge at a slower pace than in the earlier waves of the pandemic. Monitoring and understanding variants remains a key priority, as they can impact transmissibility, severity, and vaccine efficacy. The newer Pirola variant seems to be more transmissible than previous variants so there is cause for concern because of its potential to also evade previous immunity gained by the available vaccines.

BROADCASTER: What is the latest development and role of booster shots?

Booster Shots: In response to waning immunity and the emergence of new variants, many countries have initiated booster shot campaigns to reinforce protection, especially among clinically vulnerable populations.

The year 2023 has brought significant developments in the fight against the pandemic, including the introduction of new vaccines, such as Hipra's Bimervax, the vaccine being developed within the RBDCOV project. Bimervax has some unique advantages as a vaccine, it provides a broad-spectrum protection, enhanced durability, and can be more easily distributed because the vaccine does not need to be refrigerated in extremely low temperatures, which is a disadvantage of mRNA vaccines.

Whilst there have been considerable advancements in clinical trials, there are still ongoing challenges posed by new variants. Continuous monitoring of new variants is essential. This involves genetic sequencing of the virus to identify any changes in its genetic makeup. Variants of concern may exhibit increased transmissibility, resistance to existing vaccines or treatments, or altered disease severity.

As new variants emerge, it may be necessary to adapt existing vaccines to ensure they remain effective. This could involve modifying the vaccine formulations to better target specific variants or developing booster shots that provide protection against a wider range of variants.

Booster doses have become an integral part of the vaccination strategy in many countries. These additional shots are administered to enhance and prolong immunity, especially in the face of emerging variants. Booster shot regimens may need to be adjusted as new data on vaccine efficacy and variant prevalence become available. This means that the challenges posed by new variants underscore the need for ongoing vigilance, research, and international cooperation to effectively control the pandemic and prepare for future public health threats.

Global Disparities: While some regions have achieved significant progress in relation to vaccine uptake, others continue to struggle with limited vaccine access, issues around logistics, reduced infrastructure and healthcare resources, result in these ongoing challenges.

RBDCOV aims to generate robust data to demonstrate the safety and immunogenicity of this vaccine given as a booster vaccination to induce a higher and more durable immune response, for potential new variants. It should be effective in the prevention of COVID-19.

The RBDCOV benefits from the perspective of specific populations, i.e. People with immunocompromising conditions, that have been largely excluded from Phase III trials with already authorised SARS-CoV2 vaccines, as vaccine-related immune responsiveness is unclear in this population, who are at higher risk of severe COVID-19.

BROADCASTER: **And, when accessible, how do vaccines help?**

Mete Tan: Vaccination remains the most powerful tool against COVID-19. It can reduce severe cases including hospitalisation and mortality and in some emerging evidence, can also help reduce the probability of experiencing long-term effects, known as Long- Covid or PCAS (post-acute sequelae SARS-CoV-2 infection)

Despite the success of general national and international vaccination campaigns, vaccine hesitancy still remains a challenge in some communities. Effective communication and education are essential to address this by working in parternship with communities and taking into account cross-cultural issues.

Efforts to ensure equitable access to vaccines have made significant strides. Initiatives such as COVAX have facilitated the distribution of vaccines to low- and middle-income countries, although challenges still remain. This means that the need to develop fast, agile, effective delivery mechansisms for new vaccines is pertinent. [2]

Vaccination is not only about your own personal protection, but also about safeguarding your family, friends and communities. Achieving widespread immunity can only result as part of a collective effort that requires a significant portion of the population to be vaccinated. Herd immunity hinges on our collective effort to promote, encourage, and educate people about the benefits of getting vaccinated.

BROADCASTER: **Where do we need to focus our attention in future?**

Mete Tan: Variants: The evolution of the Sars-Cov virus and the potential for new variants with increased transmissibility that evade immunity, continues to be an aspect that we must stay vigilant over. Enhanced surveillance and research must remain a priority.

Long COVID: Long-term symptoms and complications of COVID-19, known as Long COVID or PACS continue to affect a significant number of individuals. Research into prevention and management is still ongoing, but we are still a long way off therapeutics as our understanding of the different disease trajectories and clusters it can take are still emerging.

BROADCASTER: **What should be considered for the future?**

Healthcare Strain: Healthcare systems have been under significant strain during the pandemic. Continued vigilance and preparedness are necessary to prevent our hospital systems from being overwhelmed and to ensure patient safety.

Public Health Measures: The effectiveness of public health measures, such as mask-wearing, social distancing, and quarantine protocols, remains crucial in controlling the spread of the virus, especially in high-risk settings such as Healthcare Facilities such as Hospitals and Clinics, Long-Term Care Facilities (Nursing homes), Correctional Facilities (Prisons and jails), Educational Institutions (Schools, colleges, and

universities), Public Transportation, Large Gatherings and Events, Indoor Dining and Bars, Close-Contact Workplaces and Travel Hubs (Airports, train stations, and bus terminals.

As we look towards the future, we are at a pivotal crossroads. Our journey against COVID-19 is far from over, and we must remain resilient, adaptable, and informed. The advancements we've discussed, Bimervax and the RBDCOV trial, are paving the way for more effective strategies.

Challenges lie ahead, with new variants emerging reminding us of the virus's adaptability. It's our responsibility to stay vigilant and committed to the ongoing Covid-19 situation. By embracing evidence-based practices, fostering collaboration, and advocating for vaccination, we can shape a future where the negative impact of COVID-19 is significantly diminished.

BROADCASTER:

What an interesting discussion! Thanks Mete! And that's everything for today! We hope you enjoyed this episode and that you join us for our next discussion with Dr. Antoni Castro Guardiola from the Girona Biomedical Research Institute (IDIBGI) and Head of the Internal Medicine department

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This is the case at the moment, but there is also the reason that some countries are no longer measuring and monitoring cases on a national level,e.g. UK. This may soon change given prediction on Pirola variant modelling already mentioned above

Episode 9 - IDIBGI: What will the direct contribution of RBDCOV be if both clinical trials are proven to be effective?

BROADCASTER:

This is the ninth episode of our podcast series and today we will be discussing what the direct contribution of RBDCOV will be if both clinical trials being carried out within the project, one with adults who have immunocompromising conditions and another with children and adolescents, are proven to be effective. To help us explore this topic, we have the privilege of welcoming Dr. Antoni Castro Guardiola, Principal Investigator Internal Medicine research group leader at the Girona Biomedical Research Institute (IDIBGI) and Head of the Internal Medicine department, Hospital Dr. Josep Trueta of Girona

Thanks Dr Antoni for being here with us today. Our question today is: **What will the direct contribution of RBDCOV be if both clinical trials are proven to be effective?**"

Antoni Castro:
If the trial results are positive, they will demonstrate that the vaccine developed by HIPRA:

- Is highly immunogenic, meaning it can generate a strong immune response in our bodies, just like it did when it was previously demonstrated in vitro (in lab tests) and in animal studies for vaccines based on the RBD (Receptor Binding Domain) fragment of the S protein. This fragment

of the S protein, is the part that allows the virus to enter human cells and is recognized by the body thanks to the vaccine.

- The HIPRA vaccine also provides a rapid immune response within the first weeks of administration by stimulating the production of neutralizing antibodies specifically targeting the RBD fragment of the S protein of the virus.
- Besides, it provides long-lasting immunity over time through the recruitment of memory CD4 and CD8 T cells, which are then capable of recognizing the SARS-CoV-2 coronavirus in the future and activating our defence system to protect against it.
- The vaccine demonstrates its immunogenic capacity also in people with immunocompromising conditions, who have weakened immune systems and are at a higher risk to severe effects from SARS-CoV-2 infection.

In addition to these immunological actions, there are also noteworthy logistical advantages compared to other vaccines, such as mRNA-based ones:

- Storage is much simpler than other vaccines as it can be done at temperatures between +2°C and +8°C. This reduces the risk of doses being mishandled due to inadequate temperature maintenance.
- Once opened, the vial remains stable even at room temperature for a minimum of 6 hours, facilitating transportation. This vaccine does not depend on complex cold chains, making it easier to reach populations in remote regions or with logistical challenges.
- The production platform of the RBDCOV project proves to be a very useful infrastructure for providing a quick response to manufacturing active vaccines against new virus variants that may emerge over time.

Therefore, if the trial results are positive, the direct contribution will be the availability of an effective and efficient vaccine for the large-scale immunization of the population against SARS-CoV-2 infection.

BROADCASTER:

Many thanks, Dr Antoni for your insights! And that's everything for today! We hope you enjoyed this episode and that you join us for our last episode with Laura Sesma from Zabala Innovation Consultancy.

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Episode 10 - ZABALA: Trial results: what are they main findings and what's next?

BROADCASTER:

This is our last episode of our podcast series. Today, we'll be talking about clinical trial results and discuss the main findings and our next steps. To help us explore this topic, we have the privilege of welcoming Laura Sesma from Zabala Innovation, the management leader in the European project, RBDCOV.

Laura Sesma: The main objective of a clinical trial is to demonstrate the **safety** and **efficacy** of the treatment that it is being tested. Safety and efficacy are tested on different phases of a clinical trial. The RBDCOV project has been created to include populations that are usually excluded from trials, such as people living with different immunocompromising conditions as well as children and adolescents. So, the project sets a unique opportunity to go beyond the traditional approaches and the main findings linked to generated data could be of outstanding importance.

RBDCOV will generate a solid and vast collection of scientific data that will allow us to depict the molecular mechanisms underlying COVID-19 infection as well as how the immune system works due to the vaccine.

Furthermore, RBDCOV project is going to provide valuable insights into the socio-economic aspects of vaccination, healthcare and medical research. Analysing clinical trials data in the context of socio-economic factors will help all stakeholders, such as researchers, healthcare professionals, and policymakers to better understand how these factors influence various aspects of healthcare and medical research.

BROADCASTER: Why data are so crucial?

Laura Sesma: Data in a clinical trial are crucial not only for assessing the clinical efficacy of an intervention and for ensuring patient safety. They are also crucial for informing regulatory decisions, advancing medical knowledge, and guiding future research and healthcare practices. Comprehensive and accurate data collection and analysis are fundamental but if data are kept in the premises of a project and are not shared with the key stakeholders the value of data get lost. In addition, it is key to strike a balance that serves both the scientific community's goals of advancing knowledge and the commercial interests of a private company that aims to exploit the results. In order to overcome this challenge and to navigate this complex terrain effectively, it is essential that we have clear policies, agreements, and fluent communication in the framework of collaboration.

Sharing the data with all the stakeholders will allow to advance science and society by working in open innovation ecosystems. If participants in a clinical trial are aware of the importance of their role -why data are obtained, what the expected results are, and even the socio-economic impact of their participation and the use of data- they will be more likely to participate and contribute to expanding knowledge and community participation. That way, it would also be possible to detect needs and demands of a targeted population in a specific disease early on. It is also crucial to make clear that the policies of the project for the use and re-use of data, are designed to de-identify sensitive patient information and that robust data anonymisation techniques are followed to minimise risks associated with re-identification.

BROADCASTER: Is data only significant for the scientific community?

The same occurs with policy makers or other decision-taking stakeholders who use the data to make decisions about the acceptance and commercialisation of a new vaccine, therapy or treatment. Data should be shared with them in forms of policy briefs or by engaging them through communication activities. It is important to engage them and offer the opportunity to access not only scientific data but also data from the perspective of the participant and the community.

We must also highlight that education on appropriate data sharing is key for the scientific community if we aim to have new generations of entrepreneurs in Europe. Scientists aim to publish in the most relevant peer-reviewed journals at international level and this could jeopardise a future commercial exploitation and, in many cases, limit this public-private partnership. So, it is necessary to clearly define and educate all the collaborators about the importance of balancing data sharing and commercial results. RBDCOV has been creating a culture of responsible data stewardship and collaboration among all the partners, each offering different perspectives.

BROADCASTER: What’s next?

Laura Sesma: The project has planted the seeds of collaboration and data sharing, so we expect that new ventures will be generated among the partners of this project. Social, scientific, technical, clinical, and industrial projects and combinations of these approaches could be initiated and help open new avenues for research and collaboration.

BROADCASTER: Thank you so much, Laura. It has been a pleasure having you here. Also, a big thank you to all the people listening to us.

We hope you enjoyed this journey together! Our podcast journey ends here but if you are eager to learn even more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV.

Thank you for staying with us!

End of the Program

BROADCASTER:

Thank you so much. It has been a pleasure having you here. Also, a big thank you to all the people listening to us.

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Thank you for staying with us!

We hope you enjoyed the beginning of this journey. Join us our next episode with (NAME) and (ORGANISATION).

And if you want to find out more about the RBDCOV project, visit www.rbdcov.eu, and follow us on our social Media Channels. You can find us on Twitter and LinkedIn with the name RBDCOV. See you next time!