

## PREGART - DISSEMINATION AND EXPLOITATION PLAN



Title of the Project: SAFETY AND EFFICACY OF DOLUTEGRAVIR AND EFV400 FOR PREGNANT AND BREAST FEEDING WOMEN: A RANDOMIZED NON-INFERIORITY CLINICAL TRIAL

Acronym: PREGART

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## 1. INTRODUCTION

This document is the deliverable 6.2 “Dissemination and Exploitation Plan” of the PREGART Project - SAFETY AND EFFICACY OF DOLUTEGRAVIR AND EFV400 FOR PREGNANT AND BREAST FEEDING WOMEN: A RANDOMIZED NON-INFERIORITY CLINICAL TRIAL (RIA2017MC-2009 PREGART) and was produced as part of the “Work Package 6 – Communication and Dissemination”. The purpose of this Dissemination and Exploitation Plan is to provide guidelines to the consortium partners. The plan provides details for the D&E actions to be undertaken during the project, as well as after it finishes and aims at harmonizing and synchronizing the individual plans by the consortium partners for the dissemination and exploitation. This document is a further and more detailed elaboration of a first draft plan presented during the Kick off Meeting and Launch of the project held in Addis Ababa (Ethiopia) in September 14<sup>th</sup>, 2019 and during the launch held in Kampala (Uganda) in January 23<sup>rd</sup>, 2020. Both draft are available in the project website (<https://www.pregart.eu/>).

## 2. BACKGROUND

### General objectives of the project

To provide evidence based recommendations for safe and effective first line ART regimens for PMTCT and treatment of HIV infected pregnant and breast feeding women living in resource limited settings. The study will contribute towards optimization of existing WHO and regional guidelines of ART for HIV infected pregnant and breast feeding women.

### Objectives of Work Package 6 – Communication and Dissemination

The main aim of WP6 – led by Istituto Superiore di Sanità (ISS) – is to communicate and disseminate project information and results. PREGART trial will produce data that would be of interest to a wide range of audiences, including researchers, patients, health care providers, community members, international organizations and policy and decision-makers. Through the communicative activity, this work package aims also to promote the use of results of PREGART in developing and revising HIV treatment guidelines for pregnant and breast feeding; in particular, as presented during the Kick off and Launch Meetings in Addis (September 2019) and Kampala (January 2020):

- ✓ Disseminate information about PREGART, its objectives and outcomes;
- ✓ Facilitate collaboration and information exchange between stakeholders, scientific communities, patient groups, the general population and international organizations such as WHO;
- ✓ Promote the use of results of PREGART in developing and revising HIV treatment guidelines for pregnant and breast feeding women;
- ✓ Create effective bilateral communication channels with stakeholders, academia, research and the public as a whole;
- ✓ Disseminate the final results (exploitation) of the project to target audiences like stakeholders, academia and researchers, and the general public.

In particular we plan to communicate the entire progress of the trial, from its initiation to its final stage and beyond to all relevant stakeholders who can potentially use the findings. Depending up on

the circumstances, the proposed communication channels used to disseminate the findings will be reviewed and updated periodically during the entire course of the trial.

### 3. STRATEGIES FOR COMMUNICATION, DISSEMINATION AND EXPLOITATION

#### What is communication?

With communication, in our project we intend taking strategic and targeted measures for promoting the action itself and its results to a multitude of audiences, including the media and the public, and possibly engaging in a two-way exchange. This in order to reach out to society as a whole and in particular to some specific audiences. Communication in this sense:

- ✓ Is strategically planned and not only ad-hoc;
- ✓ Identifies and sets clear communication objectives;
- ✓ Uses pertinent messages, right medium and means.

#### What is dissemination?

With dissemination we intend the action of public disclosure of the results by any appropriate means, including scientific publications. This include:

- ✓ Transfer of knowledge and results to the ones that can make best use;
- ✓ Maximizes the impact of research, enabling the value of results to be potentially wider than the original focus,
- ✓ Sharing essential element of all good research practices;
- ✓ Prevents results from being lost;
- ✓ Strengthens and promotes the profile of the project and the organisations involved.

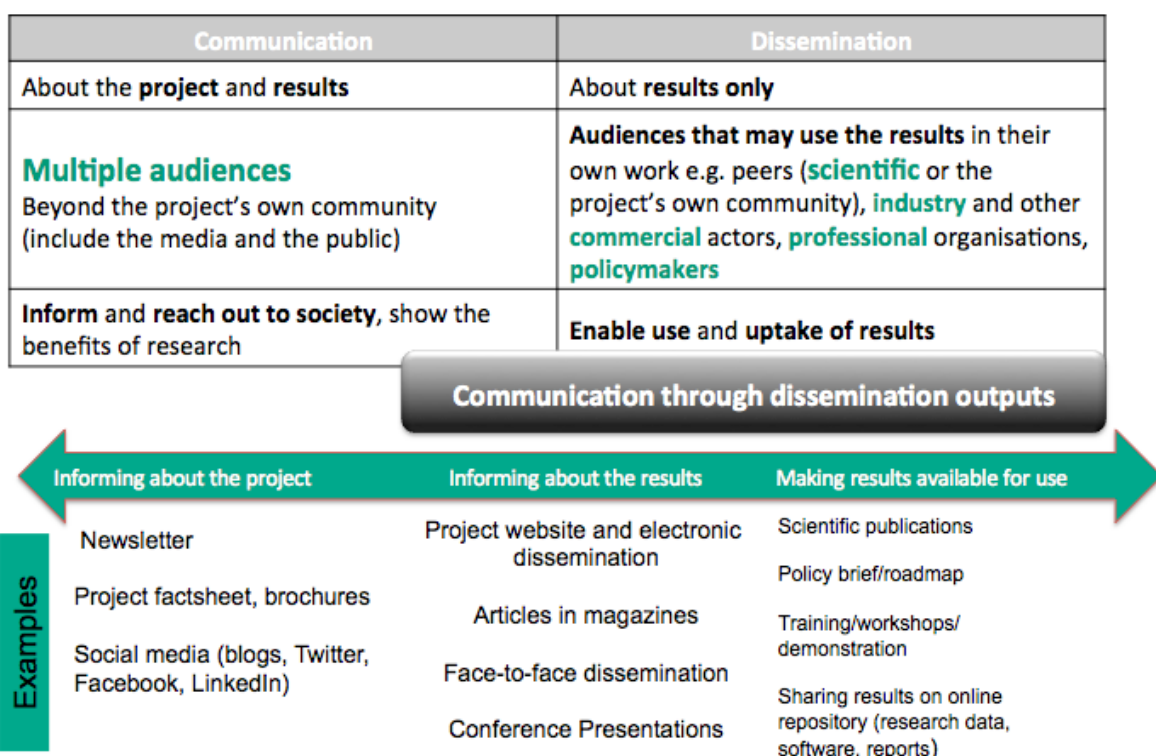
#### Communication Vs. Dissemination

Communication is a way to Inform about the project and results, reach out to society and show the benefits of research to a multiple audiences, beyond the project's own community and include the media and the public.

Dissemination is a way to enable use and uptake of results (hence it deals only with results and not with the project structure) targeting audiences that may use the results in their own work e.g. peers (scientific or the project's own community), industry and other commercial actors, professional organisations, policymakers.

The outcomes of both ways can be displayed in a continuum as follows:

## Communication Vs. Dissemination



## What is exploitation?

Exploitation is the utilisation of results in further research activities other than those covered by the action concerned, such as developing, creating and marketing a product or process, or creating and providing a service. Can be commercial, societal, political, or for improving public knowledge and action

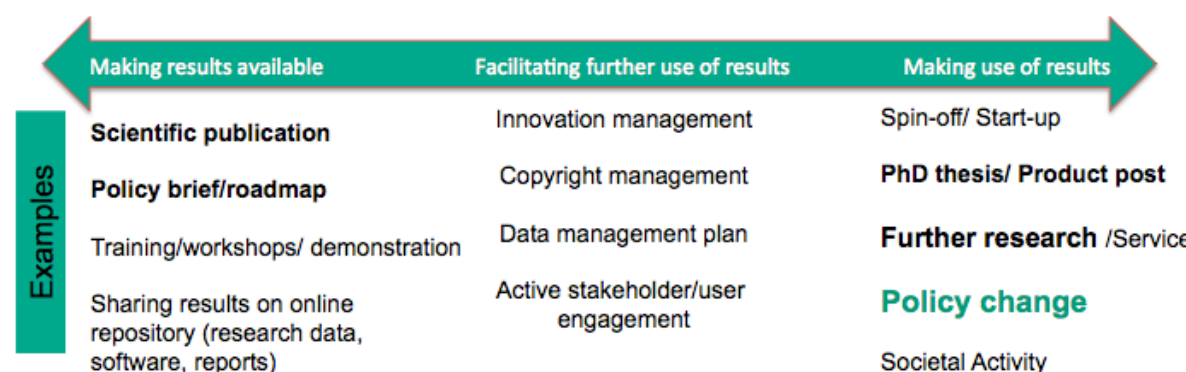
## Dissemination Vs. Exploitation

While dissemination is a way to describe and make available results – which are not restricted due to the protection of intellectual property, security rules or legitimate interests so that they can be used by the audience, Exploitation is the action to make use of results, for scientific, societal or economic purposes by groups and entities that are making concrete use of results and participant shall make best efforts to exploit the results it owns, or to have them exploited by another legal entity.

The outcomes of both ways can be displayed in a continuum as follows:

## Dissemination Vs. Exploitation

Dissemination	Exploitation
Describing and <b>making available results</b> so that they can be used	<b>Making use of results, for scientific, societal or economic purposes</b>
Audiences that <b>may make use</b> of results	Groups and entities that are making concrete use of results
<b>All results which are not restricted</b> due to the protection of intellectual property, security rules or legitimate interests	<b>All results generated during project</b> Participant shall make best efforts to exploit the results it owns, or to have them exploited by another legal entity



## 4. STRATEGIES TO COMMUNICATE WITH THE TARGETS

### Targets

As stated in the project proposal, the entire progress of the trial, from its initiation to its final stage and beyond, will be communicated to all relevant stakeholders who can potentially use the findings; they include:

- ✓ *Local and national level authorities*, including Federal Ministry of Health, Regional Health Bureaus, Zonal Health Departments, and Heads of relevant health facilities running HIV clinic.
- ✓ *Trial participants* (women who participated in the trial and their families, relatives, partners and caregivers who regularly support the patients).
- ✓ *Health facilities and health professionals (implementers)* that provide HIV/AIDS case management services are the primary users to improve the quality of services through direct clinical monitoring of their patients. The outcomes will be a good input for physicians for decision-making regarding the progress of their patients. The first instance of communication to these audiences begins with project initiation workshop conducted at the time of inception and results dissemination workshop at the end of the trial.
- ✓ The *scientific community*, through dissemination of results in the scientific literature.

- ✓ *Policy makers*: their role in promoting utilization of the outcome is unquestionable as they are the ones that influence revision of the existing treatment HIV/AIDS treatment modalities for pregnant and breast feeding women.
- ✓ The funding agency *EDCTP*.

Of course, depending up on the circumstances, the proposed communication channels used to disseminate the findings will be reviewed and updated periodically during the entire course of the trial.

The local and national level authorities have already been informed before the start of the trial through two Kick off and launch workshops respectively in Addis Ababa (Ethiopia) in September 2019 and in Kampala (Uganda) in January 2020. The outcome as well all the material presented during these occasions are already made available in the Pregart website, together with the list of important stakeholders who participated.

During the above mentioned workshops, emerged clearly the need of a full involvement of local communities and civil society organizations in the process of communicate the aim of the trial with the direct beneficiaries - trial participants (pregnant women and their families, relatives, partners and caregivers who regularly support the patients) - and hence in better involving them in the trial. We will expose later in this document our plan to cope with this important issue (sse the part titled “Local Activities / Communication at local level”).

## Internal/External - Horizontal/Vertical communication & tools

Communication is a key element of the PREGART project, necessary to achieve its main objectives, both inside and outside the consortium. Communication should be social - visual - transparent - inclusive - bottom-up - collaborative. This communication strategy, is open to changes over time, in order to adapt to possible evolutions in both the external and the internal scenario, aiming to respond to public and experts communication requirements.

PREGART strategy will therefore address two levels of communication, that can in some cases overlap, may evolve in time, but that need to be considered separately:

- 1) Internal communication within the PREGART consortium. PREGART partners have complementary perspectives, knowledge and experiences: communication among them is a sort of laboratory where capacity of inter-sectorial exchanges can be built and proofed. It aims to mutual learning in order to address effectively scientific and societal challenges;
- 2) External communication involving stakeholders (including WHO, Industry, patient groups, NGOs, etc.) and general public.

Internal/external communication strategies will also intersect with strategies for horizontal communication to other scientists and strategies for vertical communication to other stakeholders and the public, including local communities.

Strategies for horizontal communication to other scientists include the followings:

- ✓ To project members through a secure internet site
- ✓ Through project members to other scientists
- ✓ Peer reviewed publications
- ✓ Conferences

- ✓ Seminars
- ✓ Trainings
- ✓ Workshop

Strategies for vertical communication to stakeholders (including WHO, Industry, patient groups, NGOs, etc.) include:

- ✓ Reports and other publications
- ✓ Web
- ✓ Conferences
- ✓ Seminars
- ✓ Workshops

Strategies to Communicate with the Public, including local communities:

- ✓ Printed media
- ✓ Radio/TV
- ✓ Web
- ✓ Open Seminars/Lectures
- ✓ Festivals



## 5. DISSEMINATION AND EXPLOITATION MANAGEMENT

The Communication, Dissemination and Exploitation activities will be led by ISS in the person of Dr. Marco Simonelli. He is the responsible for designing the plan and for coordination the communication, dissemination and exploitation activities of the PREGART work package results and outcomes. He works in close collaboration with all the other team members and with the agency in charge of the website creation and maintenance, Zadig (see here below).

## 6. BRAND & LOGO

The PREGART consortium needs first of all to be identified as a new actor in the field of clinical trial funded by EDCTP. For this purpose ISS has started to contact several communication agencies



specialized in the creation of brand, logo and websites particularly dedicated to the communication and dissemination of research projects and has finally selected and contracted the communication company Zadig, one of the largest Italian agencies specialized in the communication of scientific and biomedical research. Zadig provides high quality information and promotes the development of new forms of communication and training, giving priority to the Internet and e-learning and develops campaigns, websites, publications, apps and newsletters targeting health operators and the general public.




With Zadig we developed a corporate image to be used in all external communication. Brand is much more than a logo; it is a coordinate way to present the project so that any product (website, deliverable, business cards, newsletters, and so on) reflects its mission, vision and values.

Since the first investigators meeting held in September in Addis Ababa, we gathered partners' ideas and suggestions, and together with the communication agency Zadig, we developed several ideas of logo. These have been shared in the course of December and January with all the PREGART partners. Some of these have been selected and further elaborated until arriving to the final version, which has been officially presented and launched during the meeting held on 23 January 2020 at the Protea Hotel Marriot in Kampala.



Some of the proposed logo

The final logo was the following:

COLOR		CMYK	RGB	#
		100% 0% 65% 0%	39 166 135	#27A687
		100% 97% 31% 39%	34 34 80	#222250
		0% 69% 100% 0%	216 113 44	#D8712C



The final logo

The image of the mother carrying the child on her back - in the typical sub-Saharan African way - stands out against the background of the African continent, and recalls the main target of the project, pregnant and breast feeding women. The colours chosen for the logo are partly linked to the

national colours of the countries where the project is implemented. The sentence on the bottom is the so-called pay-off, a sort of motto making the PREGART mission more explicit.

## 7. WEBSITE & SOCIAL MEDIA

### The website

The website is a key tool of external communication, even if it could somehow useful for internal communication as well. Its aim is to publish project deliverables and all other outputs (newsletters, ...); upload on it any products of the project (i.e. materials from meetings and workshops, leaflets, posters, pictures; report any relevant events in their country that could be of interest for the project.

The PREGART website domain has been purchased by ISS on the 19<sup>th</sup> of December 2019, [www.pregart.eu](http://www.pregart.eu). ISS took care of the relative SSL certificate for HTTPS navigation.

The graphic design of the website - coordinated with the selected logo - has been realised by Zadig with the collaboration of ISS. The site is now available, online, responsive with a graphic layout that adapts to different types of PC devices, tablets or smartphones. The site is CMS (Content Management System), chosen among the best software available in open source and able to easily manage the reserved area (according to the features required by the project) and to allow any changes to the initial structure of the site, so as to meet the different needs that could be created in the 5 years of the project.

The website will follow these communication guidelines: clarity of language, addressing both experts and the general public, transparency, interaction with different parts of society, plenty of pictures, videos, info-graphics & data-viz, and so on and will be completely open access.

It aim to contain info about the projects, update, results, articles; project deliverable and all other outputs (newsletters, ...); any products of local activities (i.e. leaflets, posters, pictures, videos),

The site currently contains the following sections

- ✓ The Project (with description of PREGART project and the trial);
- ✓ Partners;
- ✓ Work Packages;
- ✓ Documents;
- ✓ Focus;
- ✓ Contacts.
- ✓ It will have soon a reserved area (access to the reserved area is allowed through user name and password provided directly to the interested parties, according to the indications of the project contacts).

In specific it will contains these types of contents:

- ✓ a sort of library where everybody (experts, media, general public) can find key documents (abstracts and link to the source) about the thematic of the trial;
- ✓ deliverables, introduced by short abstracts;
- ✓ material presented during meetings, seminar, workshops;
- ✓ published papers;

- ✓ lessons and presentations at conferences, meetings;
- ✓ events (in a calendar);
- ✓ bulletins and newsletters;
- ✓ local activities (reports, pictures, videos, leaflets, etc..);
- ✓ special events;
- ✓ news about the project;
- ✓ press review;
- ✓ Intranet for internal use and exchange of info.



THE PROJECT PARTNERS WORK PACKAGES DOCUMENTS FOCUS CONTACTS



**Safety and efficacy of Dolutegravir and EFV400 for pregnant and breastfeeding women: a randomized non-inferiority clinical trial**

*The homepage of the website*

Zadig will also be in charge of site maintenance for 60 months. Moreover Zadig will provide ISS with editorial support for updating the site and its contents for the entire duration of the project.

## Infographics and data visualisations

Moreover Zadig will provide ISS for the creation of info-graphics and data visualizations of the project results to be included on the site. Starting from the second year, info-graphics and data visualizations concerning the project results will be realized and uploaded in the website: these includes maps with dynamic visualisation of the sites where the trial will be conducted and related information, results etc. Example of an info-graphic programme which will be used (with an infogram programme for instance), is here below:

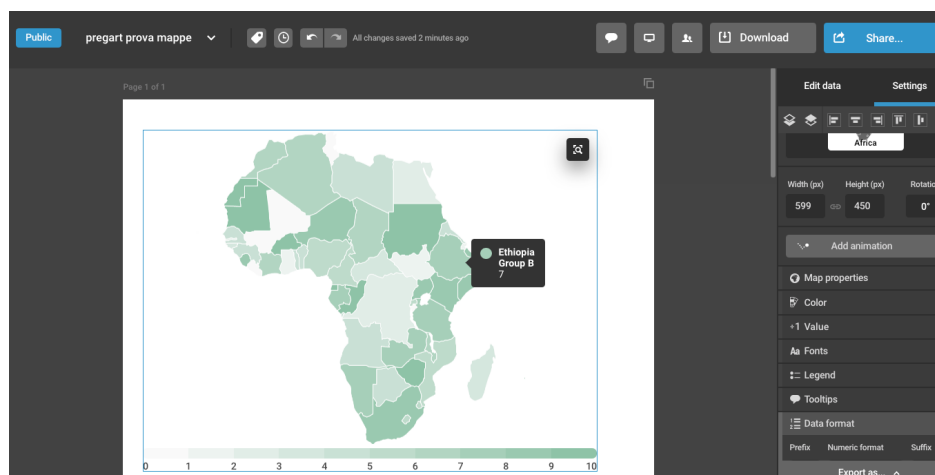


This project is part of the EDCTP2 Programme supported by the European Union RIA2017MC-2009



EDCTP





Example of info-graphic

## Social Media: Twitter account

Social networking already is part of a researchers and academic' daily routine. Social media activities within our project will notably contribute to achieve the external communication's objectives by actively involving stakeholders and public. Within the vast offer of social media we have chosen twitter, hence in January 2020 a twitter account @PregArt\_project has been opened. The twitter account – as well the website - are addressed to the audience identified in the project proposal: "a wider range of audiences with the goal of creating a platform where the findings of the trial will be implemented smoothly in the intended target population". The wide range of audience will include also journalists.

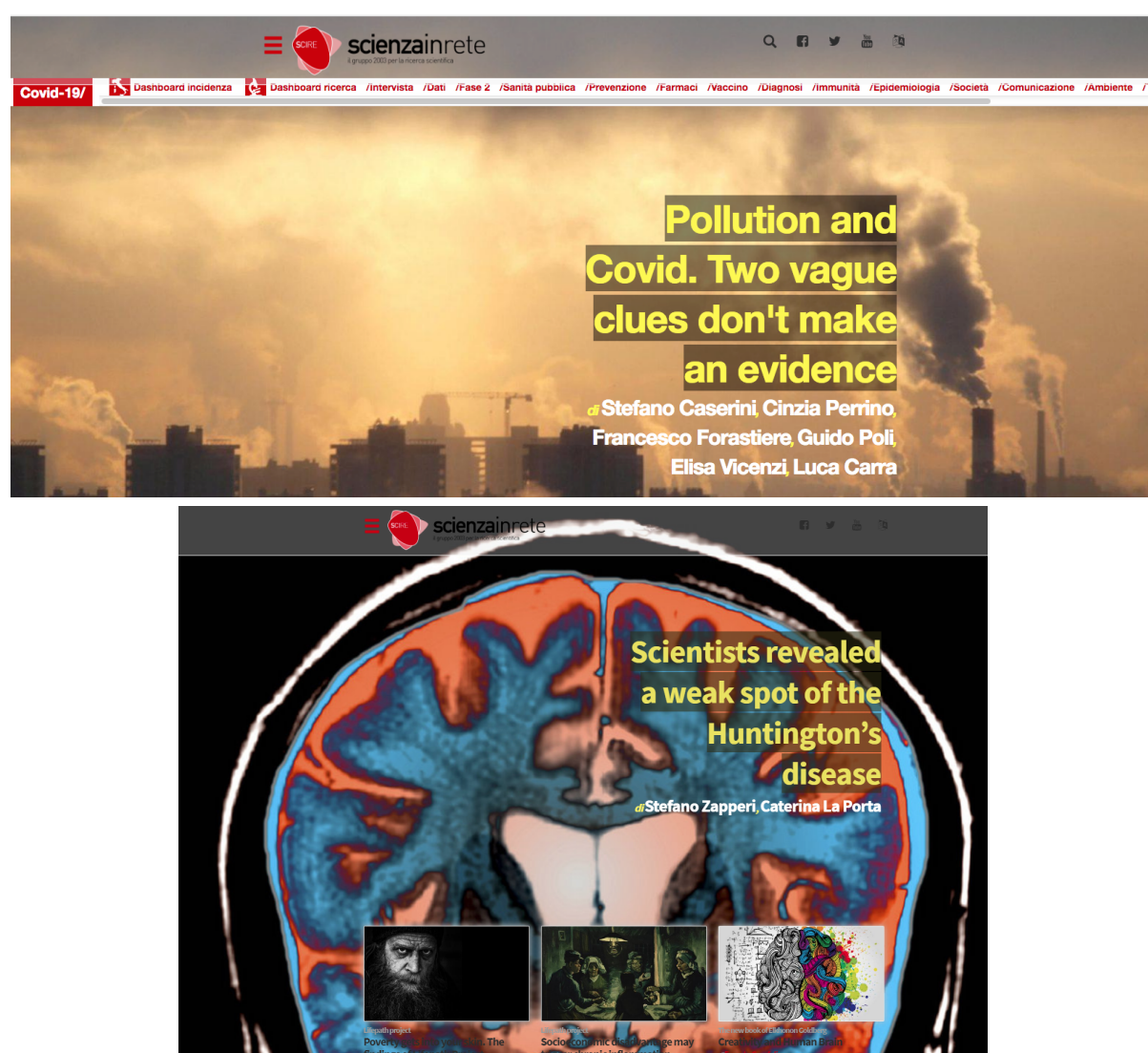


Pregart Twitter account



## 8. SCIENTIFIC COMMUNICATION

As stated in the project proposal, HIV/AIDS represents one of global public health problems. Any scientific evidence related to prevention and/or care of patients with HIV/AIDS therefore, should reach a wider range of audiences. Scientific communication to disseminate the trial outcomes will be disseminated through multiple methods, which include articles in peer reviewed international journal, which has an history of publishing trials and in other scientific journals (such as Lancet), magazines, newsletters, pamphlets, leaflets, but also seminars, workshops, meetings, festivals and web pages, reports and policy briefs. This activity starts from the second year: we plan to present outcomes through different channels (plan may be adjusted to needs and opportunities). In particular, Zadig will organize the publication of articles presenting the project on the English edition of the online journal "Science on the Net": [www.scienceonthenet.eu/](http://www.scienceonthenet.eu/)



The English edition of the online Magazine "Scienza in Rete" - <http://www.scienceonthenet.eu/>

## 9. EVENTS

Special events are of particular importance to disseminate activities and outcomes of the project. These will include:

- ✓ Edctp Conference,
- ✓ A Final Project Conference;
- ✓ Festival of Global Health Italy;
- ✓ Other according to needs and opportunities.



Some special events where we will present PREGART outcomes: The Festival of Global Health in Italy

## 10. PRINTED MATERIALS

During the second year of the project we will create, in collaboration with Zadig, layout for printed materials, as brochures and newsletters: these layout will be used as a template for all kind of printed and digital material and especially for the material which will be printed for distribution at local level. (See the dedicated section on local material).

Newsletters and press releases will be used to convey information about the project to the traditional media.

## 11. REALISATION OF VIDEO MATERIAL

In Ethiopia and Uganda there are and will certainly be many opportunities to film meetings, seminars, conferences and in particular some of the project activities at local level.

ISS in collaboration with Zadig may provide support to make a professional editing of these materials in order to contribute to the promotion and dissemination of project activities and results. The video

will be then uploaded in the website and disseminated through different channels. At this regard, ISS is developing in collaboration with Zadig, a “brand-format”, to be used for all video materials produced and to be coordinated with other (printed) material. Moreover ISS and Zadig will produce eventual short versions in form of trailers. These trailers will be uploaded in a dedicated section of the site, with references also in the home page and in the news/focus, and will then have the purpose to send back the complete videos for those who wish to see them. Actually we are working on two videos of 15 minutes each, realized by communication staff of Hawassa University, on the occasion of the first kick off and launch meeting in September 2019.

A Pregart channel will be opened soon on Youtube where we will upload all the videos available now and in the future.



THE PROJECT PARTNERS WORK PACKAGES DOCUMENTS FOCUS CONTACTS

### PREGART video presentation



*A first video realized in occasion of the launch in September 2019*

## 12. COMMUNICATION AT LOCAL LEVEL

The immediate beneficiaries of the trial findings are pregnant and breast feeding women who are part and parcel of the community. The degree to which these end users benefit from the output partly depends on the level of support they get from the family members and the community. The objective of communicating the findings with the community is to improve community's level of awareness about the trial outcomes. For this purpose, easier channels of communication that promote interaction through question and answer forums during community meetings which are held once a month (in Ethiopia) or mass media like public radio (both Ethiopia and Uganda) will be used. Such opportunities are used to convey information about the primary outcome (Viral load suppression, PMTC, drug resistance, drug side effects) of the trial at local levels. According to the project proposal a dissemination workshop will be organized to make participants aware of the findings at the end of the trial. However we believe that it is of paramount importance to communicate clearly with them since the very beginning of the trial and to inform them through appropriate means of communication in order to promote a clear understanding among direct beneficiaries. For this reason, during the Kick off and launch meeting held in Addis Ababa and Kampala, we invited representatives from local Civil Society Organizations. From them it emerged clearly the importance of a deep involvement of the civil society and the community in designing

communication and dissemination activities and material for the target group of beneficiaries and especially pregnant women and their family, relatives and communities.

To support these activities, new contacts and personnel have been identified both from Ethiopia and Uganda. In Ethiopia, contacts with HIV associations and other non-governmental organizations have been established. In Uganda, involvement of persons living with HIV/AIDS through their umbrella body under the chairmanship of Dr. Stephen Watiti and through exploitation of existing community engagement arrangements at the three trial participants recruitment sites has been made. All three sites in Uganda i.e. The Mildmay Hospital, TASO and the Joint Clinical Research Centre have got arrangements as well as protocols for specifically involving peer HIV infected mothers in dissemination HIV care and prevention activities undertaken by the sites. These arrangements will be used to disseminate information about and findings from PREGART.

We are planning to organize in the first quarter of the second year an online seminar/workshop with the aim to develop coordinated local material. The workshops will see the participation of the PIs involved in the PREGART project, part of the staff involved in the project in Ethiopia and Uganda, some of the above selected representatives of the community (HIV associations and other non-governmental organizations, persons living with HIV/AIDS), and expert from the communication agency Zadig. The main aim of the workshop will be to develop a coordinated communication always consistent in its content and form, among all the partners and in all the countries involved, under the same PREGART brand.

### 13. VISIBILITY OF EU AND EDCTP LOGOS

The European flag always appear on any related dissemination action as well the logo of the funding Agency, EDCTP. In addition to the logos, all publications must include the following text: "This project is part of the EDCTP2 Programme supported by the European Union RIA2017MC-2009".

### 14. CONCLUSION

This report details the Dissemination & Exploitation (D&E) plan for the Pregart project and forms deliverable 6.2 *Dissemination and exploitation plan*. This plan summarise the already designed strategies and describes the D&E actions already taken and it sets the frame for future actions. Therefore this document it is a tool that provides guidelines to the consortium partners and should be used with the aims of harmonizing all communication and dissemination activities both at international and national/local level.