

NEWSLETTER

02

4 FEBRUARY 2021

Created by: TES2A & IGTP

SMA TB



2021 has been a challenging year worldwide. As the COVID-19 pandemic is not over yet, it continues to impact health systems worldwide, causing a wide range of collateral damage. Nevertheless, we see dramatically decreased numbers of new TB cases all over the globe, as stated in scientific literature and Global TB report 2021, WHO. From an estimated 10 million new annual cases, numbers dropped to 7 million. Compared to 2019, in 2020, deaths due to TB have increased from 1.4 million to 1.5 million, the combined number reaching total back to the level of 2017.

Our project has also suffered due to pandemics, with having a low recruitment rate for SMA-TB Clinical Trial. And yet, we feel content with the results and achievements we have this year.

The first Periodic Technical Report (months 1 to 18) was submitted to the European Commission and was approved. Although the trial was hindered, three enrolling sites are successfully recruiting patients in South Africa and Georgia. To avoid further delays, we have made specific plans to ensure the performance of the subsequent tasks. We submitted all the deliverables and successfully achieved all the milestones for this period, and we are doing quite well with the Project performance according to the Key Performance Indicators. We submitted all the deliverables and successfully achieved all the milestones in this period. According to the Key Performance Indicators, our project is doing well and is following the plan of action.

We have already obtained many outputs from our work and have created the SMA-TB community in the Zenodo repository to give open access to most of them. Various communication and dissemination activities have also been conducted, including joint activities with other stakeholders and consortia members.

Next year will be busy for our project, as the partners will start processing the samples and data obtained within the clinical trial. We have a lot of plans already!

Please consider, if you want to know more about our work or feel you can collaborate with us – you can always get in touch! We will be very keen to make it possible. Meanwhile, we wish you a fruitful 2022 full of health, love, work and happiness!

Dr. Cristina Vilaplana, SMA-TB Project Coordinator

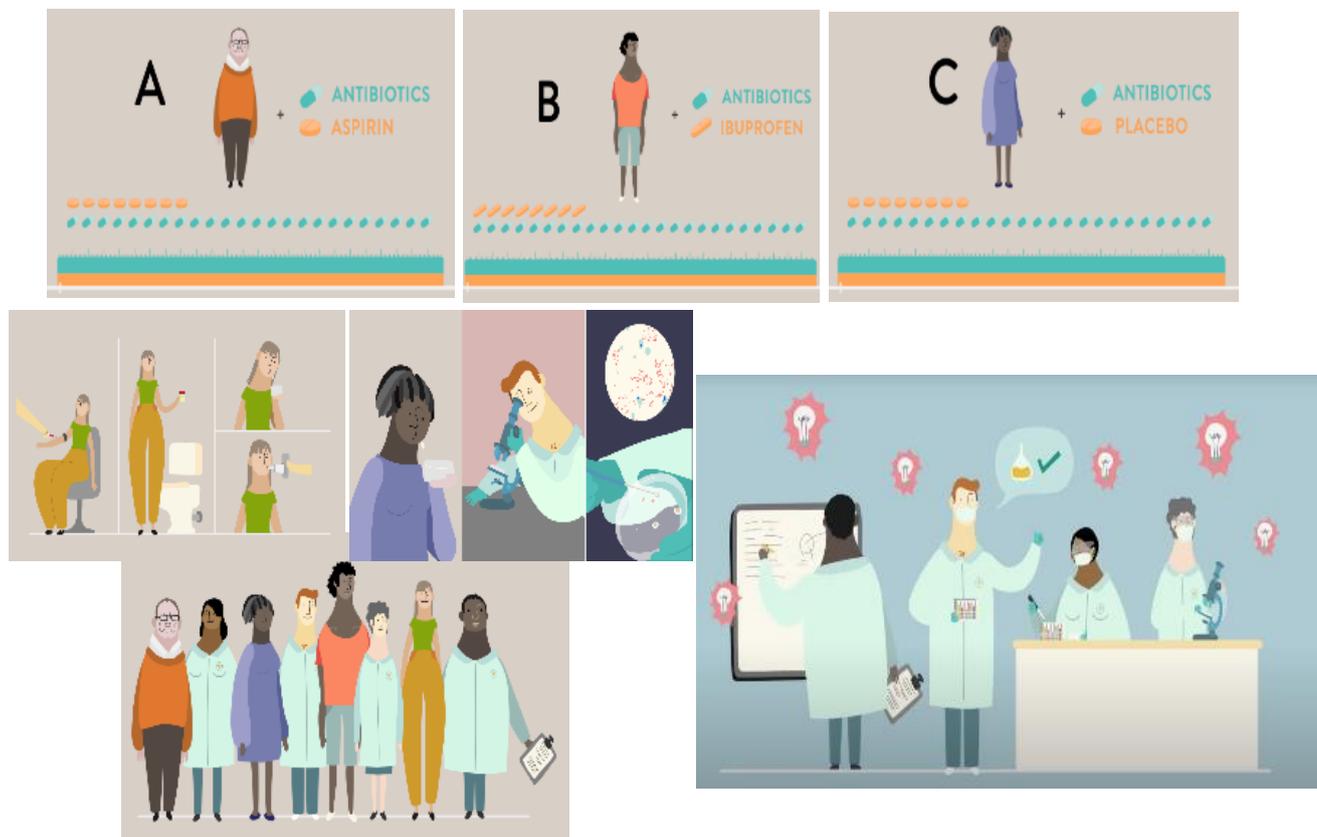
All sites enrolling patients to the SMA-TB Clinical Trial!

Big step for the SMA-TB project! First patients were enrolled in the [clinical trial](#) at South African sites, Matlosana and Soweto and Tbilisi, Georgia. We are very proud of our partners, the Perinatal HIV Research Unit (PHRU) team affiliated with the University of the Witwatersrand in South Africa and the National Center for Tuberculosis and Lung Disease (NCTLD) in Georgia. All personnel, including new staff from PHRU and NCTLD, were trained in accordance with their duties.



Participant recruitment started on March 2021 at the South African sites and in August 2021 at the Georgian site. As of January 2022, a total of 69 patients have been enrolled in the SMA-TB trial.

Thanks to the European Commission funding, this is a dream coming true! Based on the idea that hyper inflammation is responsible for the lung damage associated with unfavourable outcomes and sequelae, one of the approaches is to add anti-inflammatory agents to the current drug regimen in order to shorten the treatment course and lessen permanent lung damage. The aim of [SMA-TB CT](#) (NCT04575519) is to evaluate the potential impact of aspirin and ibuprofen (anti-inflammatory Host directed therapy) as an adjunct to standard therapy for drug-sensitive (DS) and Multi-Drug Resistant TB. This possibly will reduce tissue damage, decrease the length of the treatment and the risk of bad outcomes. The trial is a multicentre, phase IIb, placebo-controlled, randomized, 3-arm trial and, in total will involve 354 patients.



SMA-TB project repository

You might know our [website](#) and [Twitter](#) account, but to widen our audience, we have created the SMA-TB project [repository on SMA-TB Zenodo community](#). Here we have uploaded several templates generated as part of the SMA-TB Capacity-building toolkit, which others can adapt and use for Project management monitoring and Clinical Trial Monitoring. On Zenodo, you can also find the SMA-TB Clinical Trial [video](#) (which works as an electronic informed consent) and our [first newsletter](#).

We hope new uploads come soon! Please feel free to check it from time to time, find whatever is helpful to you, download it, share it, and use

SMA-TB Short Stories

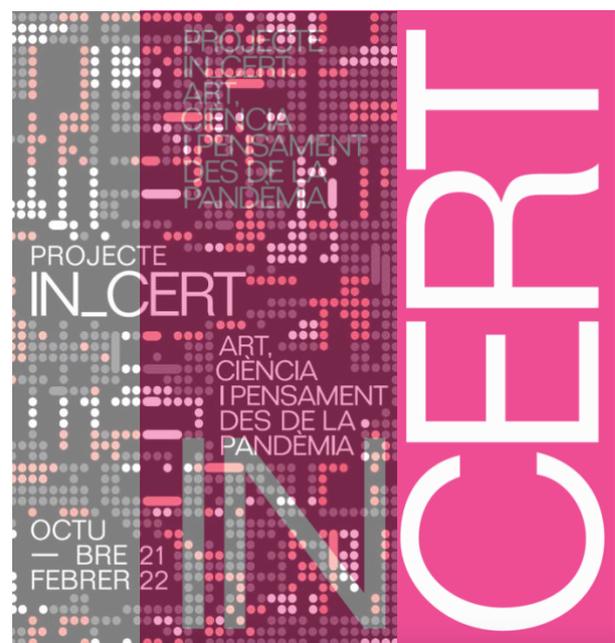
A story is an effective way to make people remember your message, to stir your audience imagination and emotions. Communication is the most effective when it takes place in environments that provide authentic social cues about how knowledge is applied.

Thus, SMA-TB has decided to produce short stories involving different stakeholders and referring to different SMA-TB project development stages. We present the first set within this newsletter, focusing on researchers and medical staff involved in SMA-TB clinical trial. Videos were recorded on both Georgian ([Youtube](#), [Zenodo](#)) and South African ([Youtube](#), [Zenodo](#)) sites.



Joint activities / other projects

As much as possible, SMA-TB is linking up with other projects funded by the Commission within the different programmes. A group of artists and scientists have been meeting this year to discuss with other professionals: infectious diseases, outbreaks, the pandemic, the lock-down, death, the limits of the science, the ethical limits of research, how we face disease, etc. Dr. Cristina Vilaplana (SMA-TB coordinator) and Dr. Roger Paredes (MISTRAL (GA N° 847943) coordinator) have been the scientists involved in the working group of this project. They have provided the perspective of tuberculosis disease and SMA-TB research (Vilaplana), HIV infection and MISTRAL research (Paredes) and how the pandemic has impacted the research. This has resulted in several public activities jointly organized by the artists and the scientists (IN_CERT Project), which is being held in several sites in Catalonia (from 29th October 2021 until February 2022). You can check the project's [program](#), [video](#), and the [catalogue](#) for further details.



SMA-TB Key Performance Indicators

SMA-TB project has defined 26 KPIs that are used to monitor the progress of the project, to detect and to correct any problem during the project execution, aiming transparency and stakeholders' engagement. Please find here below current status of each KPI.

KPI N°	NAME	Target	Current Status
KPI-01	Cycle time from IRB submit to IRB approval (in days)	160	Achieved: 134 days (in South Africa) 86 days (in Georgia) 63 days (in Spain)
KPI-02	Time from Open to enrollment until the enrollment quota is met (in months)	30	Recruitment is ongoing thus this KPI is not measurable yet
KPI-03	Trial retention	85%	94,44%
KPI-04	Prevalence of functional impairment	1,5 months	The RCT is ongoing thus these KPIs are not measurable yet
KPI-05	N of HQoL questionnaires completed	711	
KPI-06	Capacity Building tools kit	1	Achieved: The Capacity Building tools kit has been issued and up to now (M1-M18) includes up to 36 different documents generated.
KPI-07	N° of relevant biomarkers	3-5	N/A
KPI-08	Clinical and analytical validation of CD5L kit	1	Ongoing
KPI-09	Key enclaves linked to response to intervention	3-5	N/A
KPI-10	Medical algorithm for patients' stratification	1	N/A
KPI-11	Open-access publication counts	5	4: 3 open-access publications and 1 pre-print.
KPI-12	Citation Impact	10	As the articles have been published this year, their Citation Impact is not yet available
KPI-13	Co-authored analysis	20%	50%
KPI-14	Number of dissemination activities	5/year	9
KPI-15	Number of communication activities	12/year	17
KPI-16	Media citation analysis	1500	Twitter impressions = 56,722 Website total site sessions = 598 News posted on LinkedIn = 2,912
KPI-17	Stakeholders' representatives on SMA-TB governance bodies, committees and meetings	4	8
KPI-18	Meetings with policy makers	6	5

KPI-19	Resources devoted to stakeholder engagement (€),	11,500€/Y	485.07€
KPI-20	Timelines in D and M submission	<15% delay	3% for Deliverables; 59% for Milestones
KPI-21	N management meetings conducted/planned	100%	Achieved: 100%
KPI-22	Interactions with EAB	yearly	Achieved: 100%
KPI-23	Gender population in CT	50%	Males= 76,47% Females= 23,53%
KPI-24	% Promoted, recruited and retained personnel and costs	20%	30% 193.565,26€
KPI-25	Gender dimension (participants)	50%	73% females / 27% men
KPI-26	Education (education degrees)	15	Achieved: Training received by SMA-TB personnel: n° of people=68; Training given by SMA-TB personnel: n° of people=36; Education healthcare workers (training, secondments, others): n° of people=2; Education others: n° of people=3.

SMA TB

If you are interested in knowing more about the SMA-TB project or want to collaborate, please do not hesitate to contact us:

smatb@igtp.cat

www.smatb.eu



This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 847762