SOBERANA

Business Virtual Forum

2021

"Cuba and Germany. Possibilities for cooperation in the biotechnology sector"

German Office for the Promotion of Trade and Investment in Cuba
Cuban Chamber of Commerce
BioCubaFarma

IFV INSTITUTO FINLAY DE VACUNAS

MSc. Indira Utria Torres
Business Specialist

A scientific institution honoring Dr. Carlos Juan Finlay

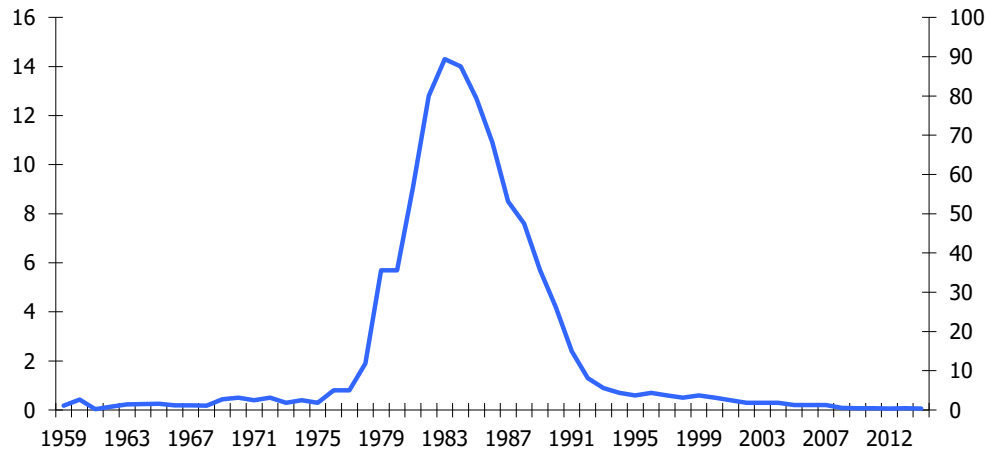
- Closed Cycle Platform

R+D
Production
QA / QC
Clinical Evaluation
Commercialization

Pharmaceutical, biological, biotechnological and chemical synthesis preparations, mainly **VACCINES**

- Infectious diseases vaccines
- Conjugate vaccines
- Synthetic Vaccines
- Combined vaccines
- Active Pharmaceutical Ingredients

VA-MENGOC-BC®

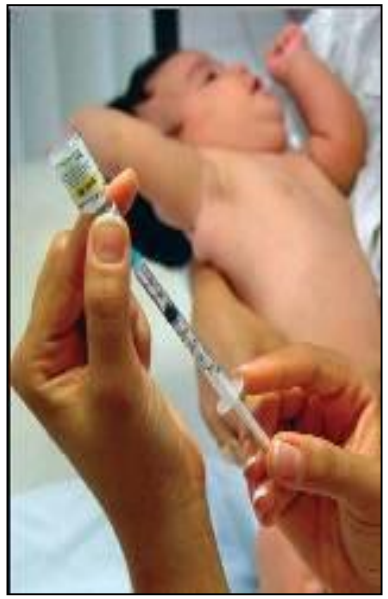


- Vaccine against meningococcal diseases
- Mass application in Cuba start in 1984
- An excellent control of serogroup B meningitis
- License in more than 17 countries, an apply to control outbreaks in Brazil, Colombia, Uruguay and Vietnam
- More than 60 million doses apply in Latin-America
- WIPO Gold Medal Patent

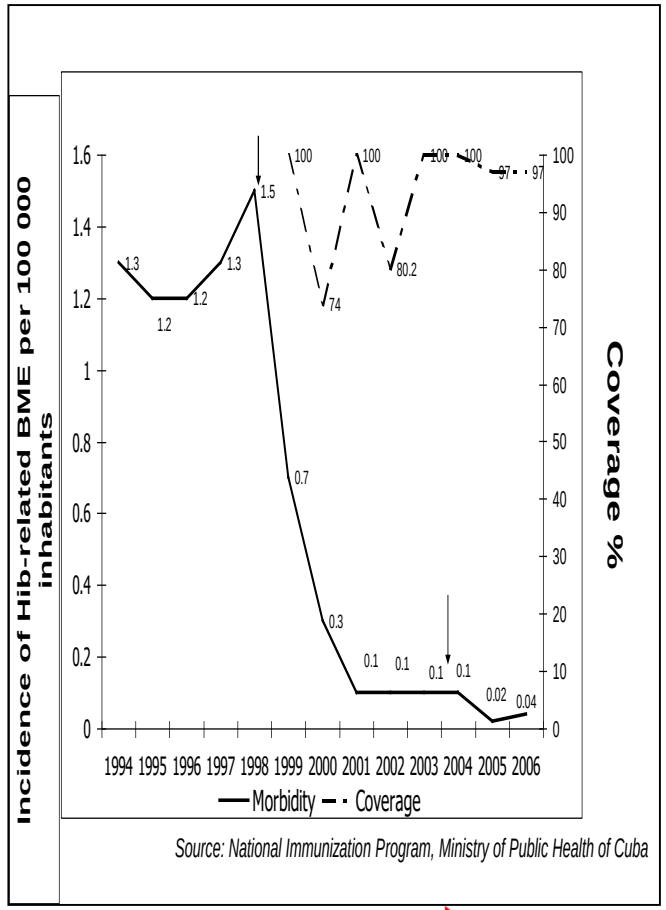
Cuba

Quimi-Hib®

- Vaccine vs *Haemophilus influenzae* type b
- The first vaccine with a synthetic antigen produced and commercialized since 2004
- Synthetic chemistry to obtain Hib oligosaccharides has been become a competitive technology for conjugate vaccine production



- WIPO Gold Medal Patent 2005 WP 01/16146 USA, EPO, Australia, China.
- 2005 Award Tech Museum for Innovation



Cuban Immunization Program

- Against 13 diseases
- Vaccination coverage: More than 98%
- Population high immune level

ESQUEMA NACIONAL DE VACUNACIÓN DE CUBA.

Vacuna / Protege	Edad de la dosis 1ª	2ª	3ª	Reactivación	Dosis (ml)	Vía	Región de aplicación	Lugar de aplicación
BCG* / Tuberculosis	Al nacer	---	---	---	0,05	ID	Deltoides Izquierdo	Maternidad
Heberbiovac HB* / Hepatitis B	Al nacer	---	---	---	0,5	IM	1/3 medio de la cara antero - lateral del muslo	Maternidad
Heberpenta-L /Difteria, Tosferina, Tétanos, Hepatitis B y Haemophilus Influenzae Tipo B	2 m	4 m	6 m	18 m	0,5	IM	1/3 medio de la cara antero - lateral del muslo. A los 18 M en el Deltoides	Policlínicos
VA-MENGOC-BC / Meningococo B y C	3 m	5 m	---	---	0,5	IM	1/3 medio de la cara antero - lateral del muslo	Policlínicos
IPV / Poliomielitis	4 m	8 m	---	---	0,1	ID	Deltoides Derecho	Policlínicos
DTP-VAC* / Difteria, Tétanos y Tosferina	2 m	4 m	6 m	18 m	0,5	IM	Deltoides	Policlínicos
Quimi-Hib* / Haemophilus Influenzae Tipo B.	2 m	4 m	6 m	18 m	0,5	IM	Deltoides	Policlínicos
PRS / Parotiditis, Rubéola y Sarampión	12 m	---	---	6 años	0,5	SC	Deltoides	Policlínicos y Escuelas
VA-DIFTET / Difteria y Tétanos	---	---	---	6 años	0,5	IM	Deltoides	Escuelas
Vax-TYVI /Fiebre Tifoidea	10 años	---	---	13 y 16 años	0,5	IM	Deltoides	Escuelas
Vax-TET / Tétanos	---	---	---	14 años	0,5	IM	Deltoides	Escuelas
OPV / Poliomielitis	En campaña anual. Niños menores de tres años y 9 años.				2 gotas	Oral	---	Policlínicos y Consultorios

* Los hijos de madres positivas al antígeno de superficie de la Hepatitis B, se vacunarán con BCG a los 3 meses de nacidos. Se les aplicarán 4 dosis de vacuna de la Hepatitis B (al nacer, 1 mes, 2 meses y al año) y se reactivará a los 18 meses, con DPT y Hib. EL resto de las vacunas según el esquema.

- 11 vaccines
- 8 - Cuba Production
- 6 - IFV Production

Heberpenta®

CENTRO DE INGENIERÍA GENÉTICA Y BIOTECNOLOGÍA

4 components

Combined diphtheria, tetanus, cellular pertussis, hepatitis B and Haemophilus influenzae type b vaccine. Heberpenta was introduced in the Cuban's immunization program in September, 2006.

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Projects

- ❑Pneumococcal conjugate vaccine program
- ❑Meningococcal meningitis vaccine program
- ❑Pertussis conjugate vaccines
- ❑Diarrheal vaccine program
- ❑Cancer vaccine program

Quimi-Vio®

BIOCUBA FARMA

- ❑Against *Streptococcus Pneumoniae*
- ❑Heptavalent Conjugate Vaccine (serotypes 6B, 14, 18C, 19F, 23F, 1 and 5)
- ❑Cost-Effectiveness
- ❑Tetanus Toxoid as carrier protein + AlPO4
- ❑More than 300 analytical controls per batch
- ❑More than 20 clinical studies (Clinical Trials, surveillance studies, economic and impact evaluations studies)
- ❑Current Status: Concluded Phase II-III Clinical Trials for children 1-5 years old

Ongoing Phase II-III Clinical Trials for infants

Cuba

SOBERANA MAIN MILESTONES

May 19th 2020

Project reorganization for the obtention of the specific IFV Covid-19 vaccine

August 24th 2020

Begining

1st Soberana 01

Clinical Trial

October 2020

Begining

Soberana 02

Phase I Clinical Trial

December 2020

Begining

Soberana 02

Phase II Clinical Trial

February 2021

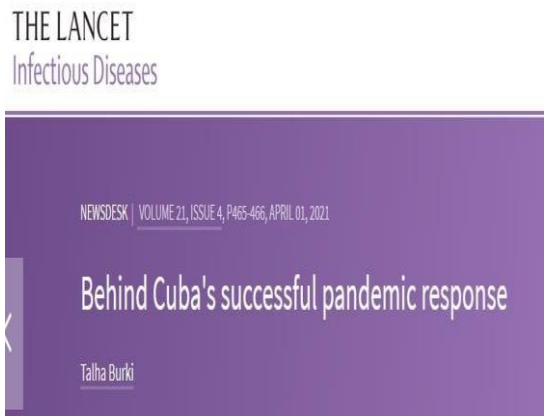
Production of the first batchs 150 000 doses scale of Soberana 02

March 3rd 2021

Begining

Soberana 02 Phase III Clinical Trial

9 months



First vaccine candidate vs COVID-19 in Latin- America and Caribbean registrated in the WHO draft

STRATEGIC ALLIANCE AMONG BIOCUBAFARMA INSTITUTIONS AND MINISTRY OF CUBAN HEALTH

SOBERANA®01

SOBERANA®02

SOBERANA®Plus

IFV
INSTITUTO FINLAY DE VACUNAS

SIMILARITIES & DIFFERENCES

BIOCUBA FARMA

- ❑ Subunit vaccine
- ❑ Receptor Binding Domain (RBD) of SARS-Cov-2 Coronavirus
- ❑ Storage conditions: 2-8 oC

SOBERANA®01	SOBERANA®02	SOBERANA®Plus
RBD + OMV + $Al(OH)_3$	*RBD + Tetanus Toxoid + $Al(OH)_3$*	*RBD + $Al(OH)_3$*
Unconjugated vaccine	*Conjugate Vaccine*	*Booster vaccine* *Unconjugted vaccine*
Healthy volunteers	*Healthy volunteers*	✓ *Convalescents* ✓ *Volunteers with primary vaccination with other formulation*

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SOBERANA®01

BIOCUBA
FARMA

- 1st Cuban and Latin-American vaccine candidate vs SARS-CoV-2 virus included in the WHO draft

- Well kown and safety platform

- Potential efficacty both infants and elderly population
- Patent application submitted
- Current Status: Concluded Phase I Clinical Trial. In process of approval Phase II-III Clinical Trials (adults) and Phase I-II Clinical Trials (pediatric population)

Cuba

IFV
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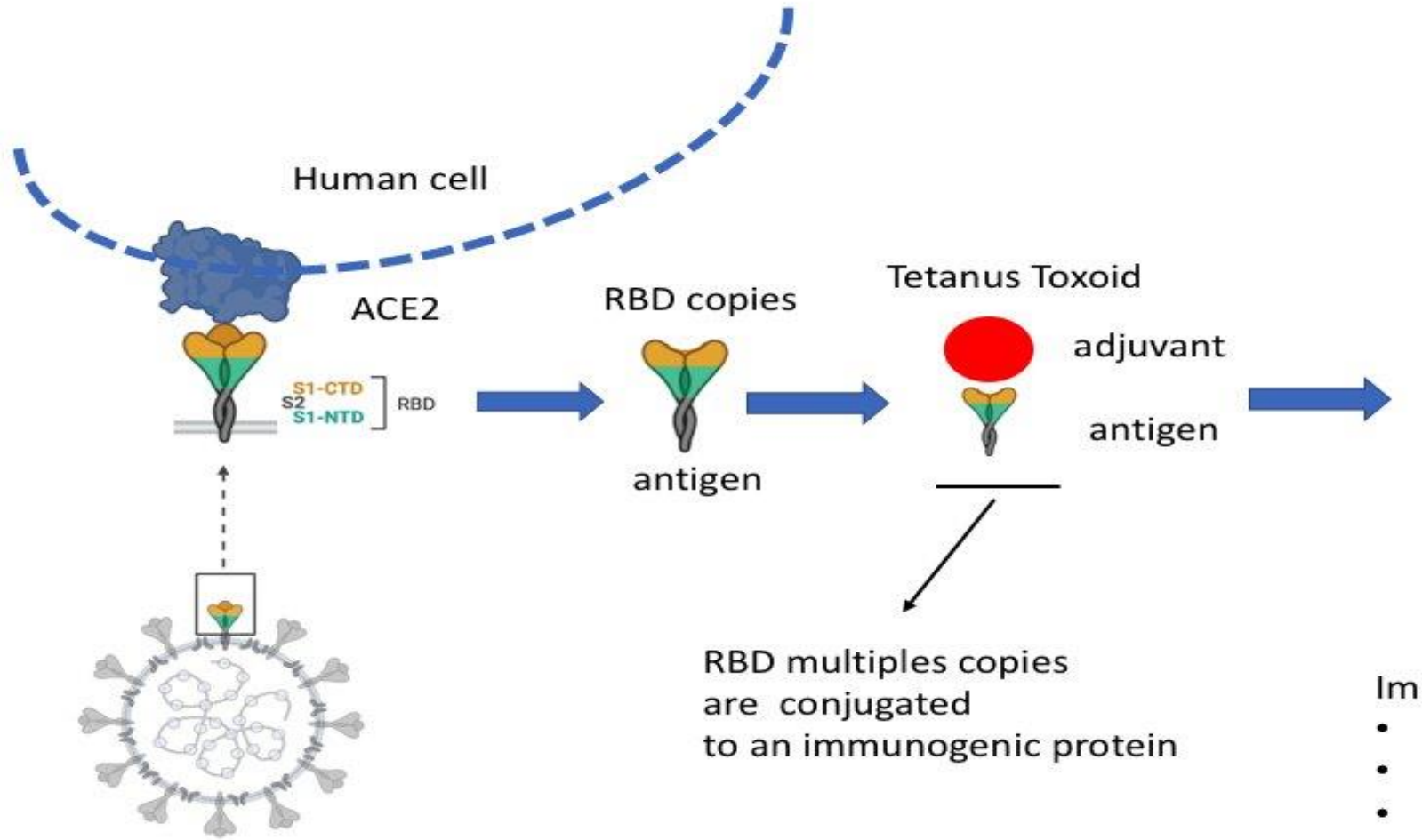
SOBERANA®02

BIOCUBA
FARMA

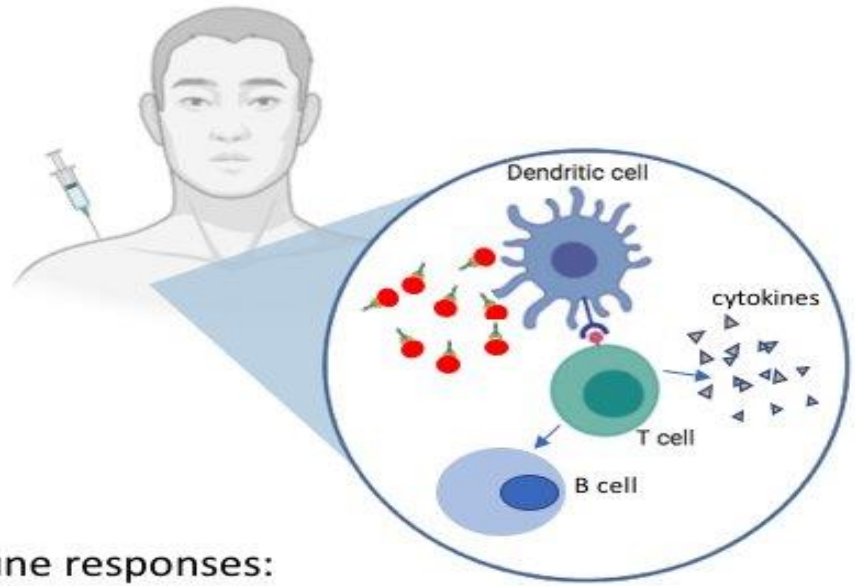
FINLAY-FR-2 Soberana 2

How it works?

Vaccine type: conjugated to immunogenic protein/carrier



RBD multiples copies
are conjugated
to an immunogenic protein



Immune responses:

- Innate = IFN
- Humoral = antibodies against RBD
- Cellular mediate = B and T cells against RBD

IFV
INSTITUTO FINLAY
DE VACUNAS

SOBERANA®02

BIOCUBA
FARMA

- ❑1st and only conjugate vaccine vs SARS-CoV-2 virus in the world
- ❑2nd Cuban and Latin-American vaccine vs SARS-CoV-2 virus included in the WHO draft
- ❑1st Cuban and Latin-American vaccine vs SARS-CoV-2 virus to begin Phase II and Phase III Clinical Trials

Quimi-Vio®

- ❑Well Known and safety platform
- ❑Innovative vaccine candidate. Patent application submited
- ❑Current Status: Ongoing Phase III Clinical Trial. In process of approval Phase I-II Clinical Trials (pediatric population)
- ❑Publications

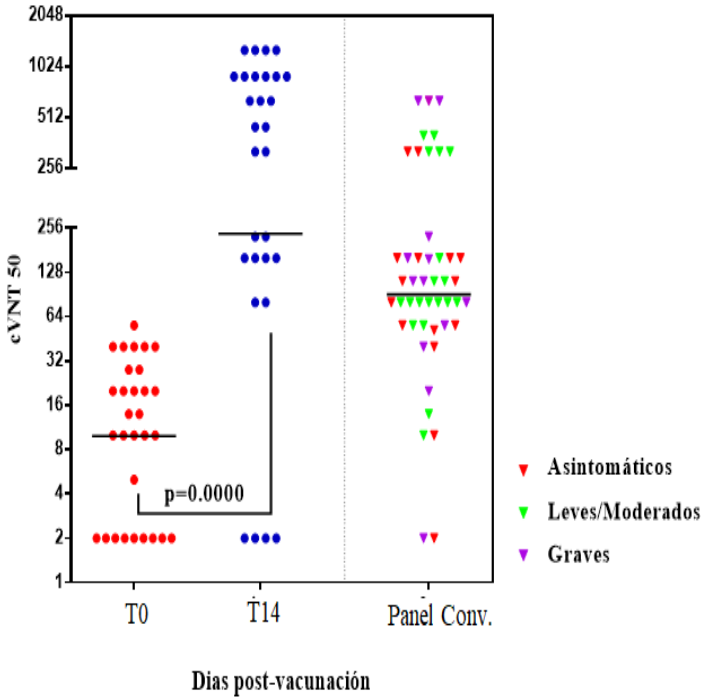
Cuba

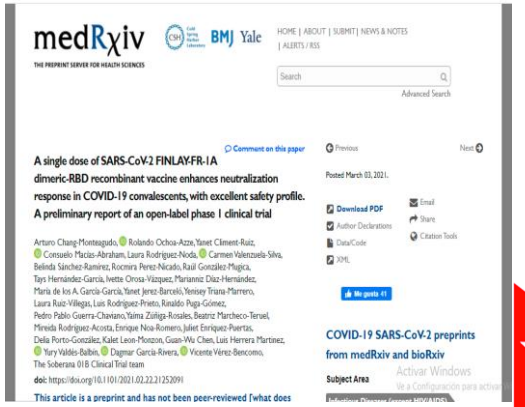
SOBERANA®Plus

- Capable of reactivating a pre-existing immune response in COVID-19 Convalescents and individuals with primo-vaccination with other formulation
- Induces an important neutralizing response after a single dose
- 1st vaccine vs SARS-CoV-2 virus in convalescents registered with Phase I and Phase II Clinical Trials in the world
- Potential booster vaccine for protection vs mutant strains
- Patent aplication submitted
- Current status: Phase II Clinical Trial in Convalescents approved by CECMED

As a booster vaccine with Soberana®02- Ongoing Phase II & III Clinical Trials

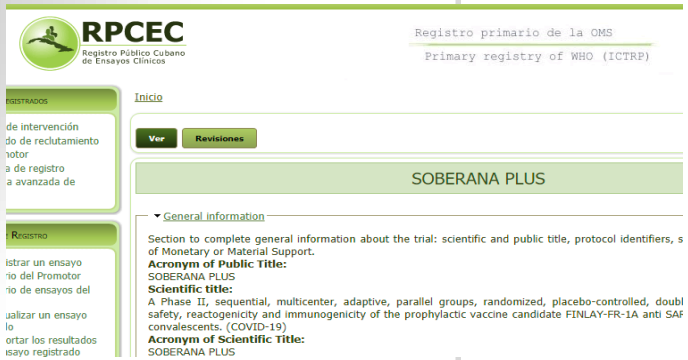
- Publications

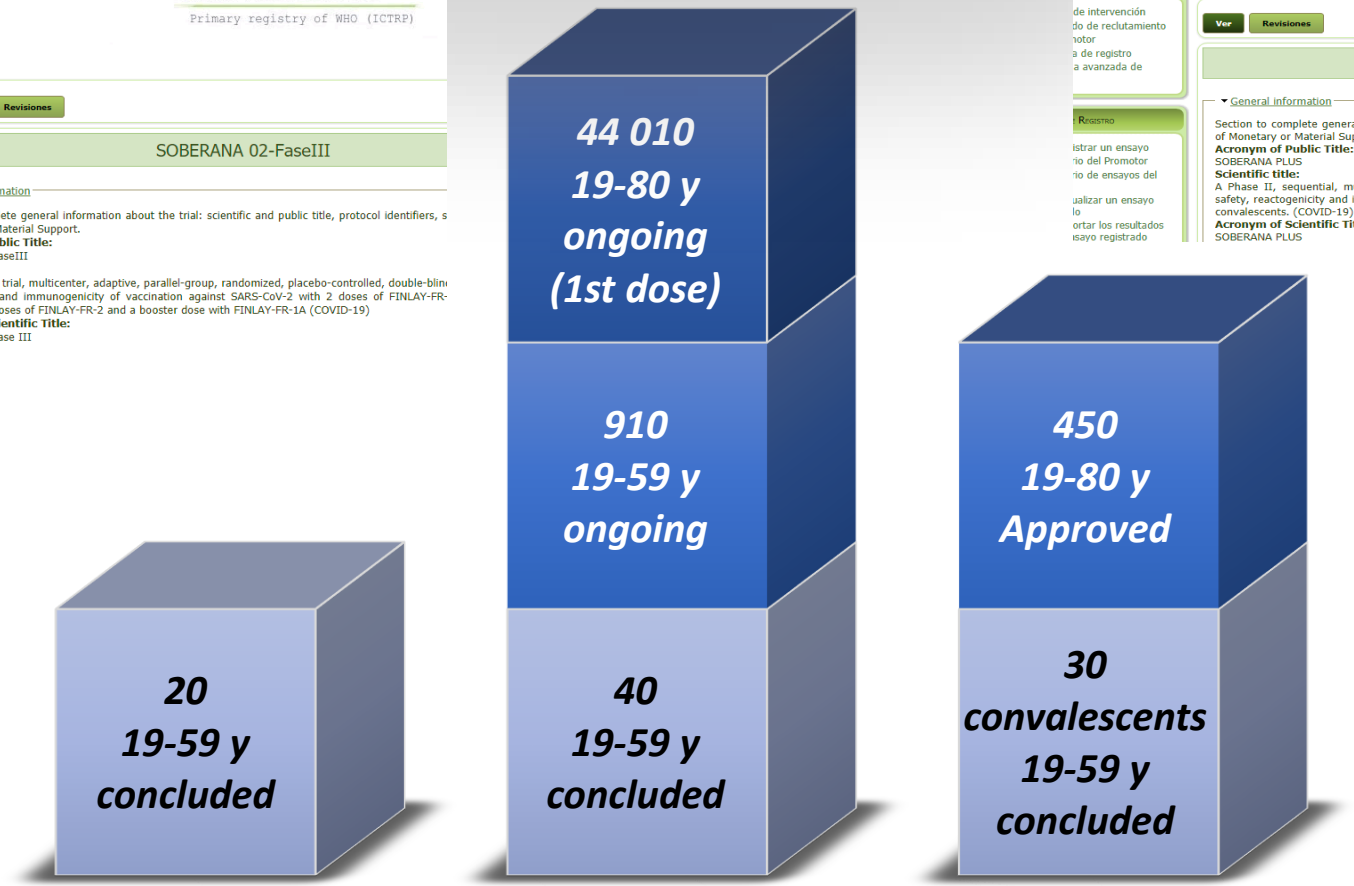




Clinical Trials

Phase I Phase II Phase III





SOBERANA®01 SOBERANA®02 SOBERANA®Plus

- High standard of Safety and Immunogenicity
- No severe and serious Adverse Events
- Very few mild Adverse Events

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FARMA

Thank you!

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