



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



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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

Dedicated to saving lives



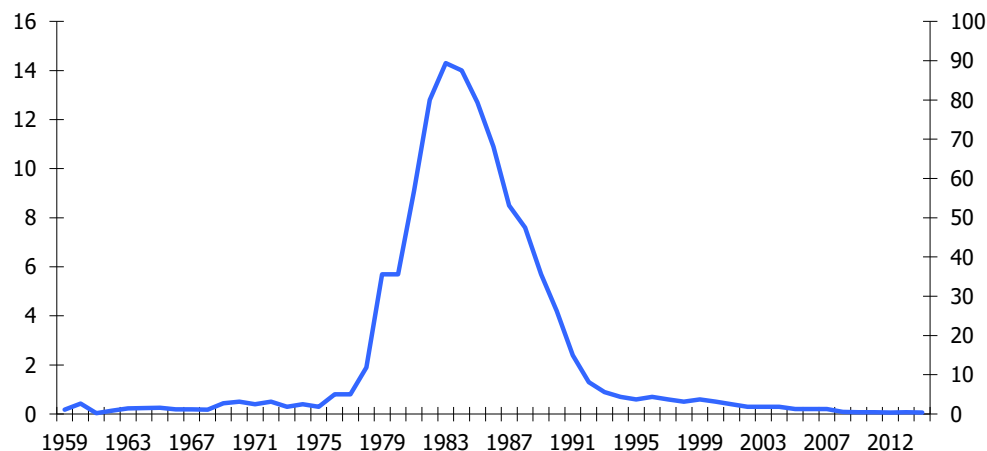
More than 30 years

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

VA-MENGOC-BC[®]



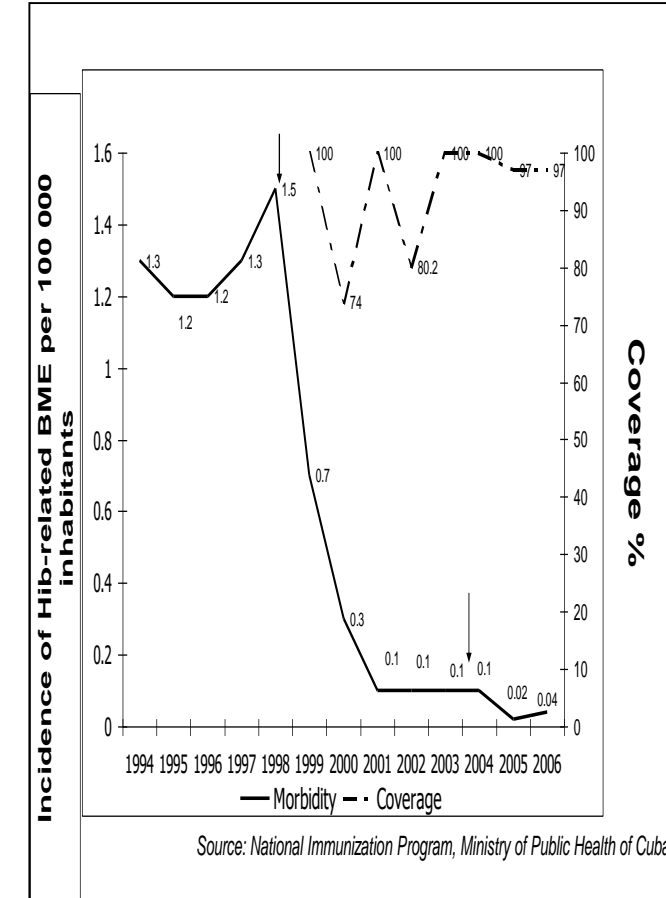
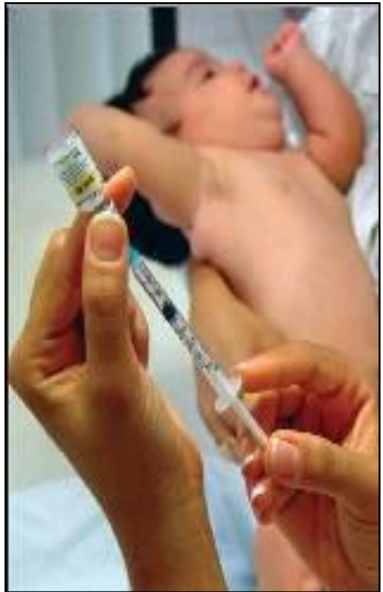
- ☐ Vaccine against meningococcal diseases
- ☐ Mass application in Cuba start in 1984
- ☐ An excellent control of serogroup B meningitis
- ☐ License in more than 17 countries, an apply to control outbreaks in Brazil, Colombia, Uruguay and Vietnam
- ☐ More than 60 million doses apply in Latin-America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





- ❑ 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				Dosis (ml)	Vía	Región de aplicación	Lugar de aplicación
	1ª	2ª	3ª	Reactivación				
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, 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 Toserina	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 -  INSTITUTO FINLAY DE VACUNAS 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.



Projects

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

Quimi-Vio[®]

- ☐ Heptavalent Conjugate Vaccine vs *Streptococcus Pneumoniae* (serotypes 6B, 14, 18C, 19F, 23F, 1 and 5)

- ☐ Cost-Effectiveness

- ☐ Tetanus Toxoid as carrier protein + AlPO₄

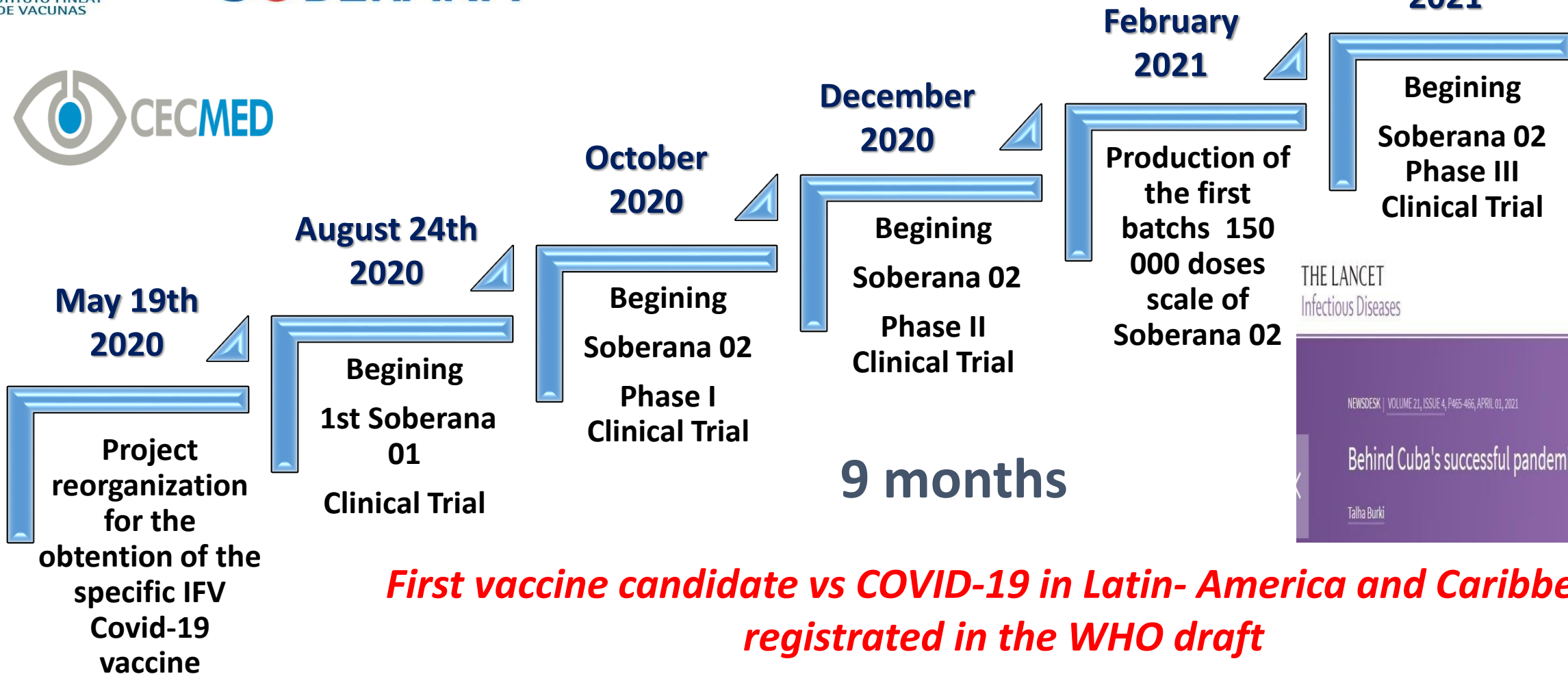
- ☐ + 300 analytical controls per batch

- ☐ + 20 clinical studies

- ☐ Current Status: Concluded Phase II-III Clinical Trials for children 1-5 years old

Ongoing Phase II-III Clinical Trials for infants





STRATEGIC ALLIANCE AMONG BIOCUBAFARMA INSTITUTIONS AND MINISTRY OF CUBAN HEALTH



SOBERANA

SOBERANA[®]01

SOBERANA[®]02

SOBERANA[®]Plus



#CienciaCubana
#CubaPorLaVida





SIMILARITIES & DIFFERENCES



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

SOBERANA[®]01

SOBERANA[®]02

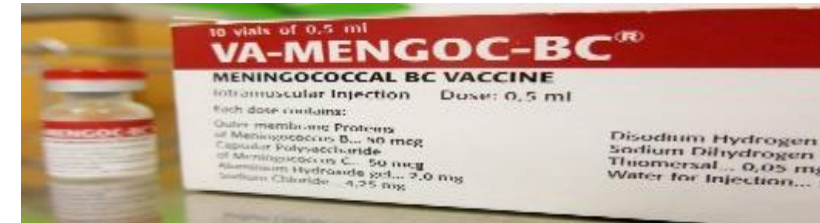
SOBERANA[®]Plus

<i>RBD + OMV + Al(OH)₃</i>	<i>RBD + Tetanus Toxoid + Al(OH)₃</i>	<i>RBD + Al(OH)₃</i>
<i>OMV Adjuvated vaccine</i>	<i>Conjugate Vaccine</i>	<i>Booster vaccine</i> <i>Unconjugated vaccine</i>
<i>Healthy volunteers</i>	<i>Healthy volunteers</i>	<ul style="list-style-type: none"> ✓ <i>Convalescents</i> ✓ <i>Volunteers with primary vaccination with other formulation</i>

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



❑ Well known and safety platform



❑ Potential efficacy both infants and elderly population

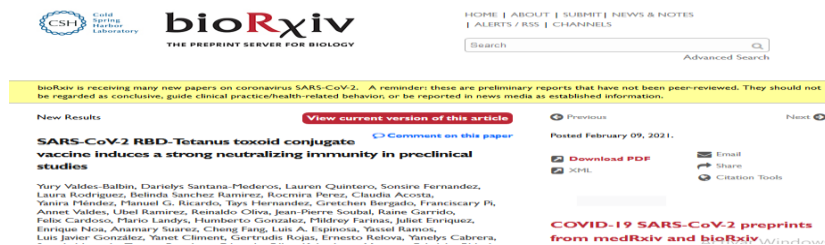
❑ Patent application submitted

❑ 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)

- ❑ 1st and only conjugate vaccine vs SARS-CoV-2 virus in the world. 1st Cuban and Latin-American vaccine to begin Phase II and Phase III Clinical Trials
- ❑ Potential long-term immune response due to the induction of T and B cell memories
- ❑ Potential efficacy both infants and elderly population



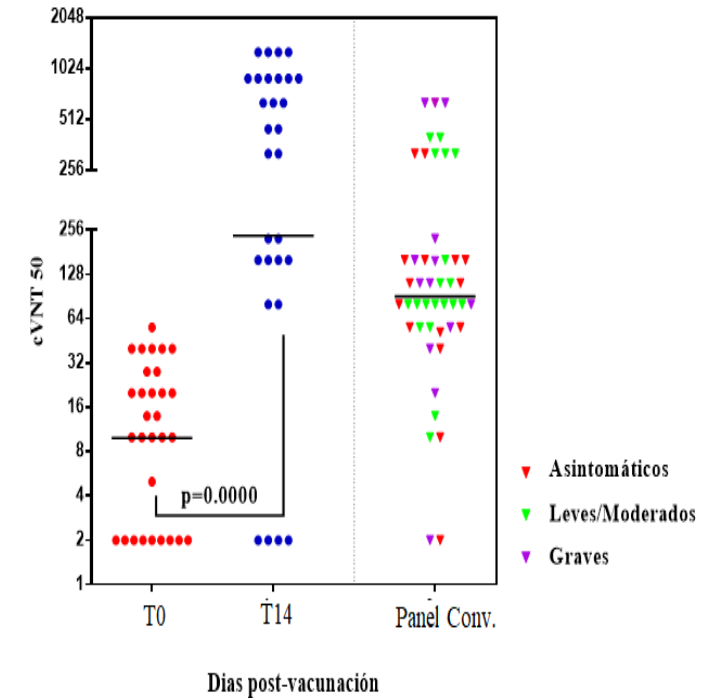
- ❑ Well Known and safety platform
- ❑ Innovative vaccine candidate. Patent application submitted
- ❑ Current Status: Ongoing Phase III Clinical Trial. In process of approval Phase I-II Clinical Trials (pediatric population)
- ❑ Publications



- ☐ Useful for boosting 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 in primed individuals
- ☐ 1st vaccine vs SARS-CoV-2 virus in convalescents with Phase I and Phase II Clinical Trials in the world
- ☐ Potential booster vaccine for protection vs mutant strains
- ☐ Patent application submitted
- ☐ Current status: Phase II Clinical Trial in Convalescents approved by CECMED

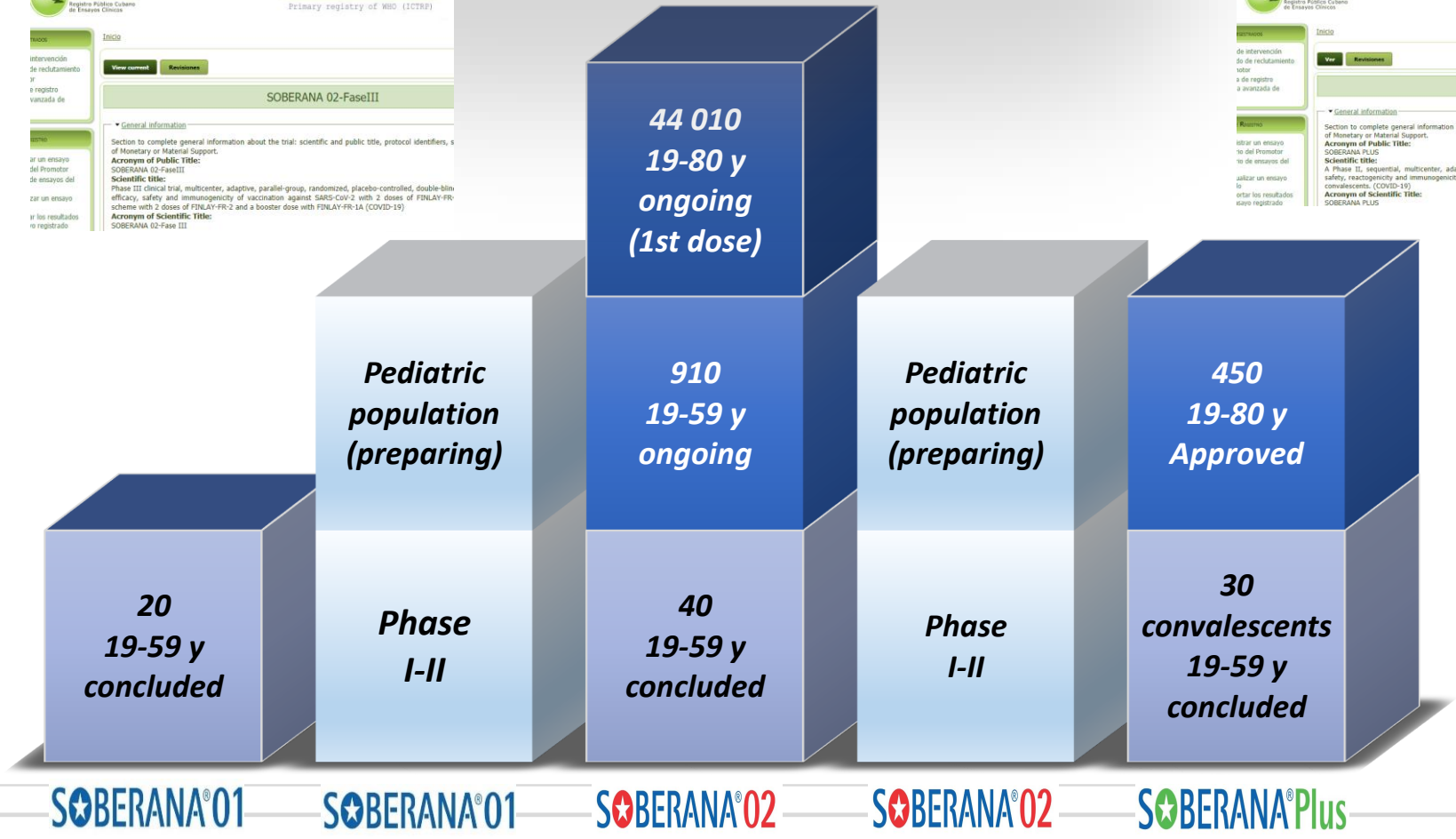
As a booster vaccine with Soberana®02- Ongoing Phase II & III Clinical Trials

- ☐ Publications



Clinical Trials

Phase I Phase II Phase III



- Good profile of Safety and Immunogenicity
- Any serious related- adverse events

Thank you!

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#CubaSalva

