



## A collage of various newspaper clippings related to the COVID-19 pandemic. The clippings are overlapping and feature headlines such as "Coronavirus fears", "Deaths top 630", "Crisis", "Six deaths", "Face masks", "Outbreak", "Cases", "diagnosed", "new testing labs loom", "Virus hotline open", "Outbreak", "cases", "positive for virus", "Ship raised", "state of emergency for COVID-19", "Coronavirus", "Worldwide", "Crisis", "response", "Six deaths", "Face masks", "Outbreak", "cases", "positive for virus", "Ship raised", "state of emergency for COVID-19", "Coronavirus", "Worldwide", "Crisis", "response", "Six deaths", "Face masks", "Outbreak", "cases", "positive for virus". The clippings are arranged in a way that suggests a sense of urgency and widespread concern.

## 3C – Sysvir Technology

- Challenge

- ❖ Global Variant

- ❖ Failing Efficacy

- ❖ Safety

- Unique Technology Opportunity

- ❖ Effective systemic treatment action for COVID-19 variant's .

- ❖ Hybrid Action Therapy

- ❖ 128 Years of Drug Existence repurposed for COVID-19

**WelBio® Clinical Guidance**





## Product Kit

- Wrist wearable medical device - emits low level light therapy
- Sub-lingual drug consisting of Methylene Blue



## Dosing

- Drug - 1ml sublingual administered once a day + low level light therapy wristband placed on the wrist
- Activated for 10 minutes with Low Level Light Therapy before being placed sublingually and After Dosing for 50min
- **Repeat cycle:** 60min Light therapy x 1ml drug x 7 days.

## WelBlo<sup>®</sup> Curative Line for Mild to Moderate Condition

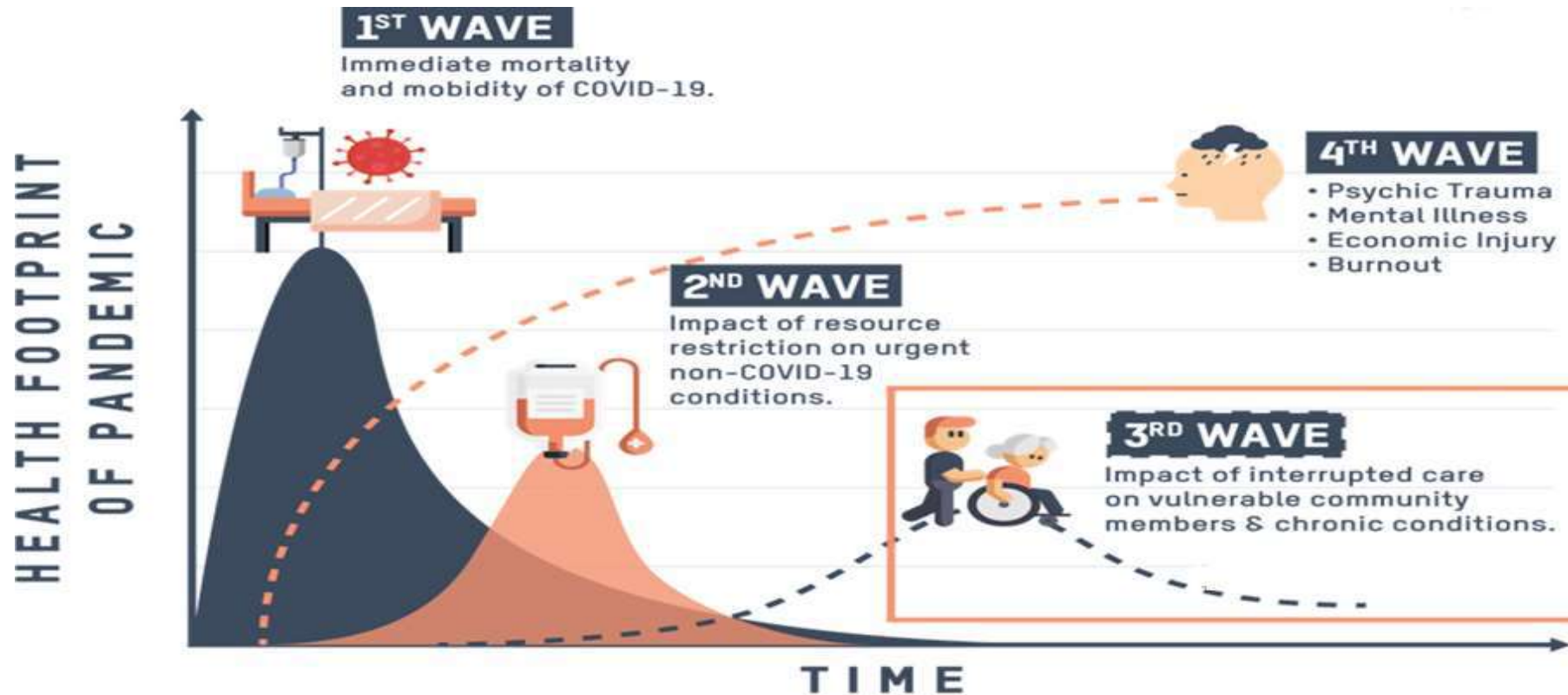


### WelBlo<sup>®</sup> technology

Technology based on approved drug and transformation

- All Active and Excipient levels as per GRAS & FDA IIG limits
- No risk of developing resistance against variant
- Sublingual delivery for faster absorption and quick action
- Ease of Administration

# Covid- 19 Burden On Human Lives Globally

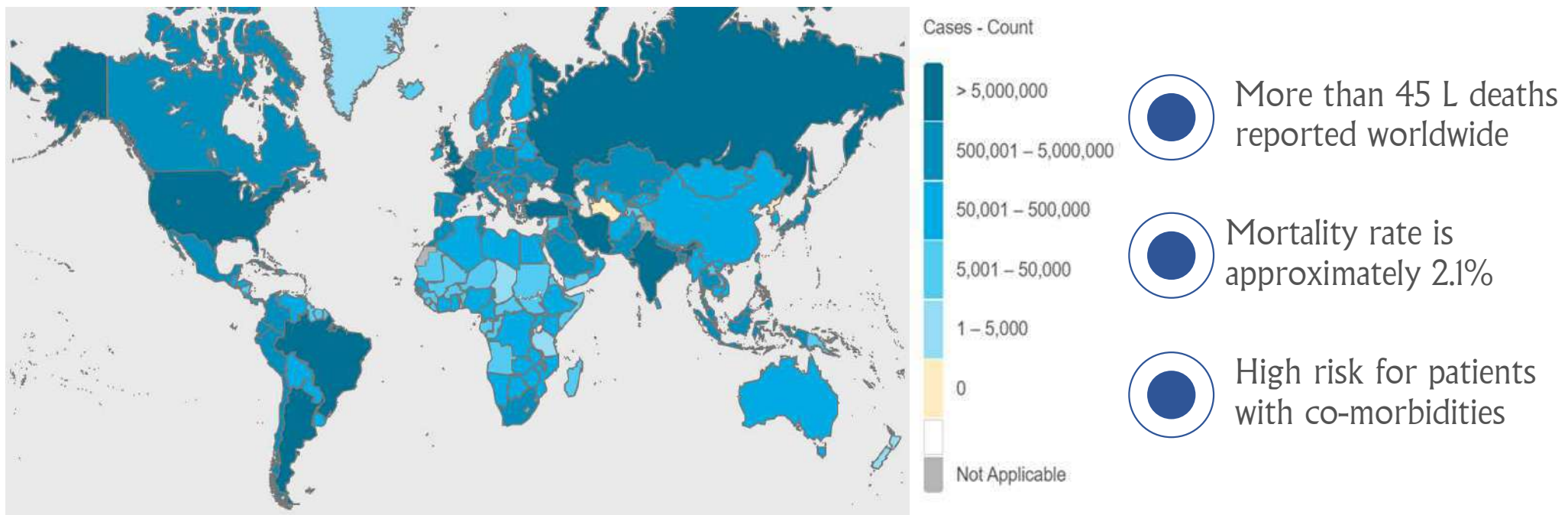


## Overview

- Why **WelBlo**<sup>®</sup> - An Essential Technology Product with acute medical value for COVID-19.
- Academic & regulatory recognition of **WelBlo**<sup>®</sup> content & Importance
- What would be impact of scheduling **WelBlo**<sup>®</sup>
- Conclusion & Recommendations.

# COVID -19 Pandemic & Its Impact

Globally, there have been more than 21 Cr confirmed cases of COVID-19.



World Health Organization. Available at:  
<https://covid19.who.int/> Accessed on: 05/09/2021.

# COVID-19 Variants & 3D Image Views

## WHO renames SARS-CoV-2 variants From alpha to lambda

### Variants of concern

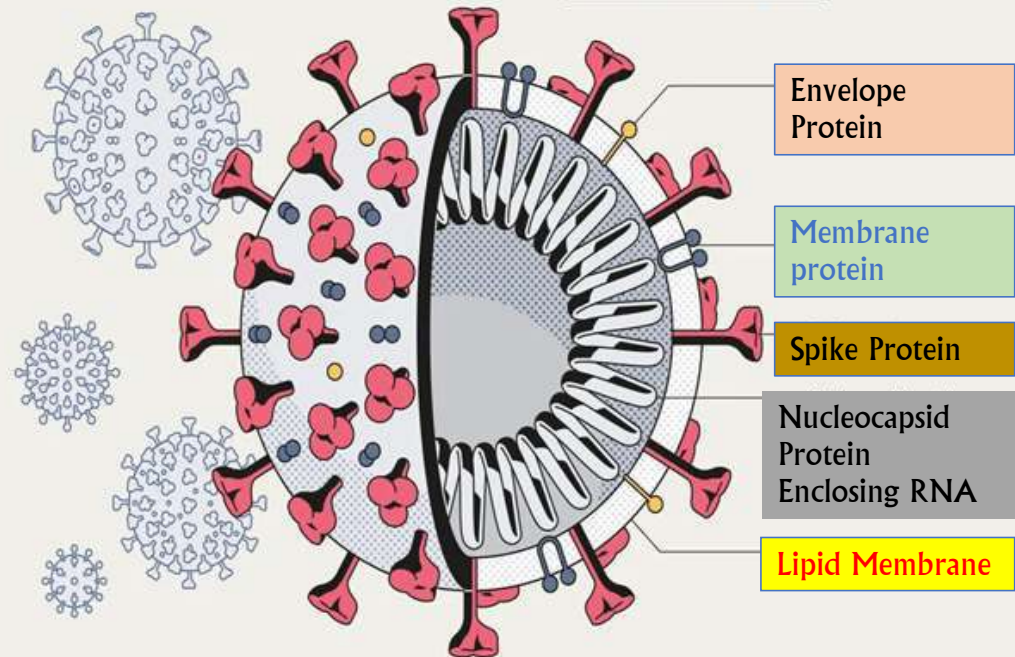
WHO label	Lineage	First documented samples
<b>α</b> Alpha	B.1.1.7	UK Sep. 2020
<b>β</b> Beta	B.1.351	South Africa May 2020
<b>γ</b> Gamma	P.1	Brazil Nov. 2020
<b>δ</b> Delta	B.1.617.2	India Oct. 2020

### Variants of interest

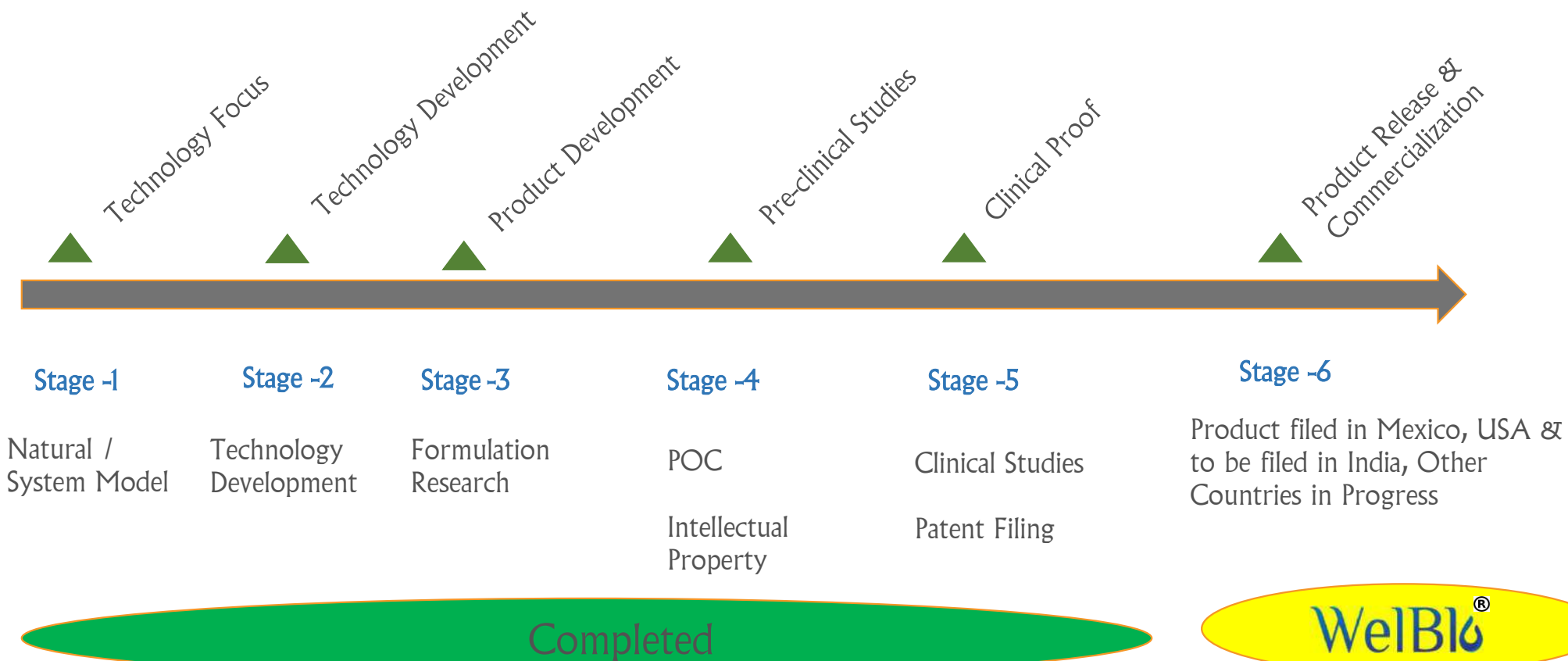
<b>ε</b> Epsilon	B.1.427/ B.1.429	USA Mar. 2020
<b>ζ</b> Zeta	P.2	Brazil Apr. 2020
<b>η</b> Eta	B.1.525	Multiple Dec. 2020
<b>θ</b> Theta	P.3	Philippines Jan. 2021
<b>ι</b> Iota	B.1.526	USA Nov. 2020
<b>κ</b> Kappa	B.1.617.1	India Oct. 2020
<b>λ</b> Lambda	C.37	Peru Aug. 2020

Source: WHO

Corona Virus 3D Image

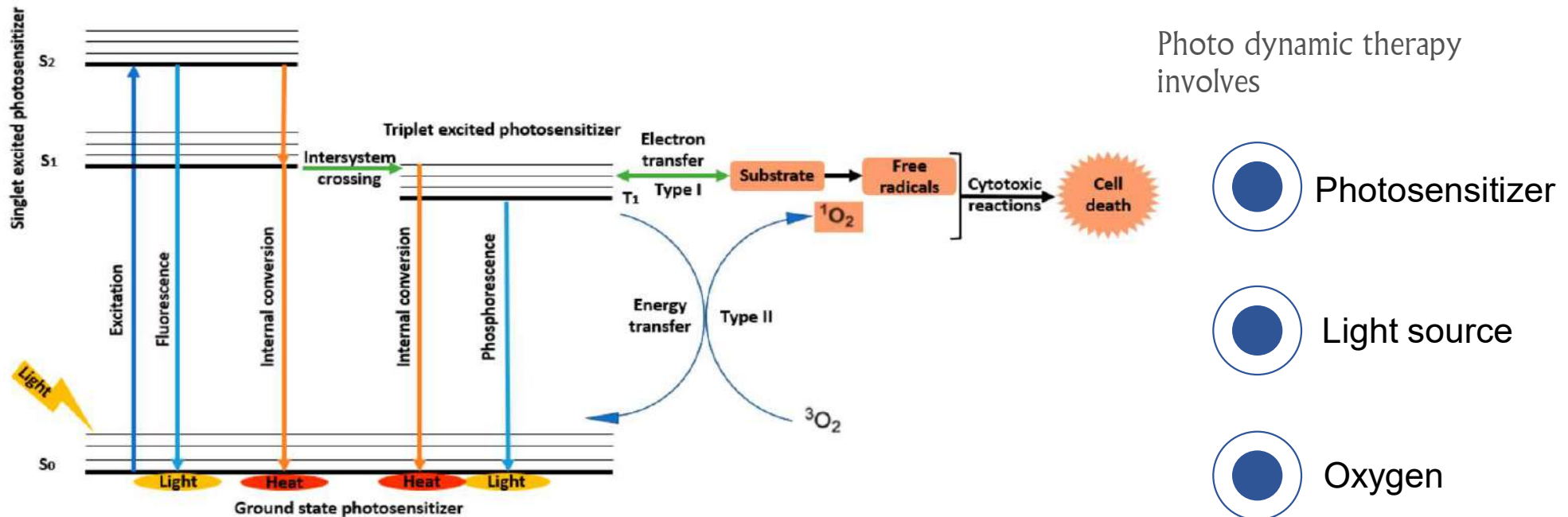


# Focelie's 3C - Sysvir Technology Development



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# 3C- Sysvir Technology Based on Photodynamic Therapy



The PDT involves generation of cytotoxic reactive oxygen species thereby producing irreversible damage to microorganisms by rupturing the cell membrane and causing cell death by necrosis or apoptosis

# 3C - Sysvir Technology

## Novel



IN vivo- redox cycling Amplification via systemic route and allowing benefit of ionic , non ionic state of molecule efficacy with adjuvant effect tissue regeneration. Work against mutation in lipid enveloped viruses

## Validated



Full fledged Clinical Trial Completed in America

## Innovation



Reducing oxidative stress impact by infection overcome through Accelerating drug in three line of action on Human Machinery shield against corona virus machinery.

## First to Market



**WelBio®** developed from 3C - Sysvir technology Non Invasive & Self Administrative therapy.

## MB-Repurposed The WelBlo® Way

Intravenous  
10mg/ml

Liquid 1%

Topical 2%

Topical 2%

No Device

No Device

No Device

No Device

WelBlo®  
5mg/ml

PDT

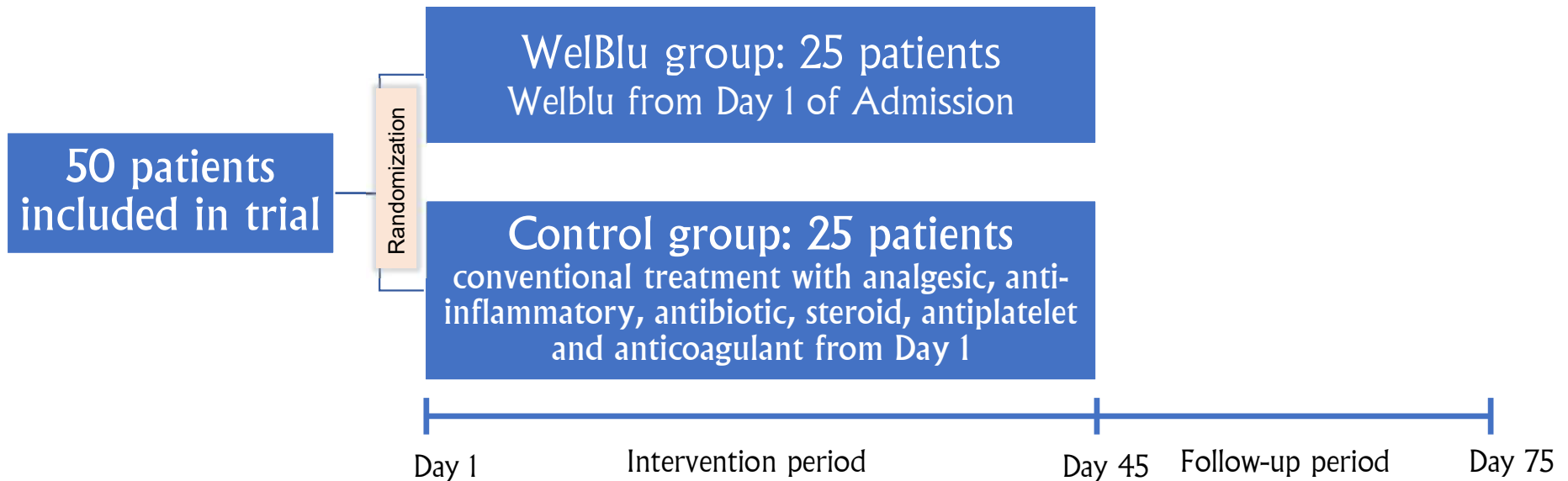
## Global Market Product Dosage - MB

## WelBio® - Clinical Study Objective

Clinical Study Design : Randomized Prospective & Longitudinal Clinical Trial

- Establish the final systematization of the application of novel therapy to combat the COVID-19 pandemic.
- Decrease viral load by SARS-CoV2 in patients with mild COVID-19 disease.
- Decrease morbidity and pulmonary sequelae in COVID-19 patients

# Clinical Study – Design



## Outcomes:

- PCR is negative three days in a row.
- An expected recovery: 70% - intervention and 30% - non-intervention group.

# WelBio<sup>®</sup> Study – Patient Selection Criteria

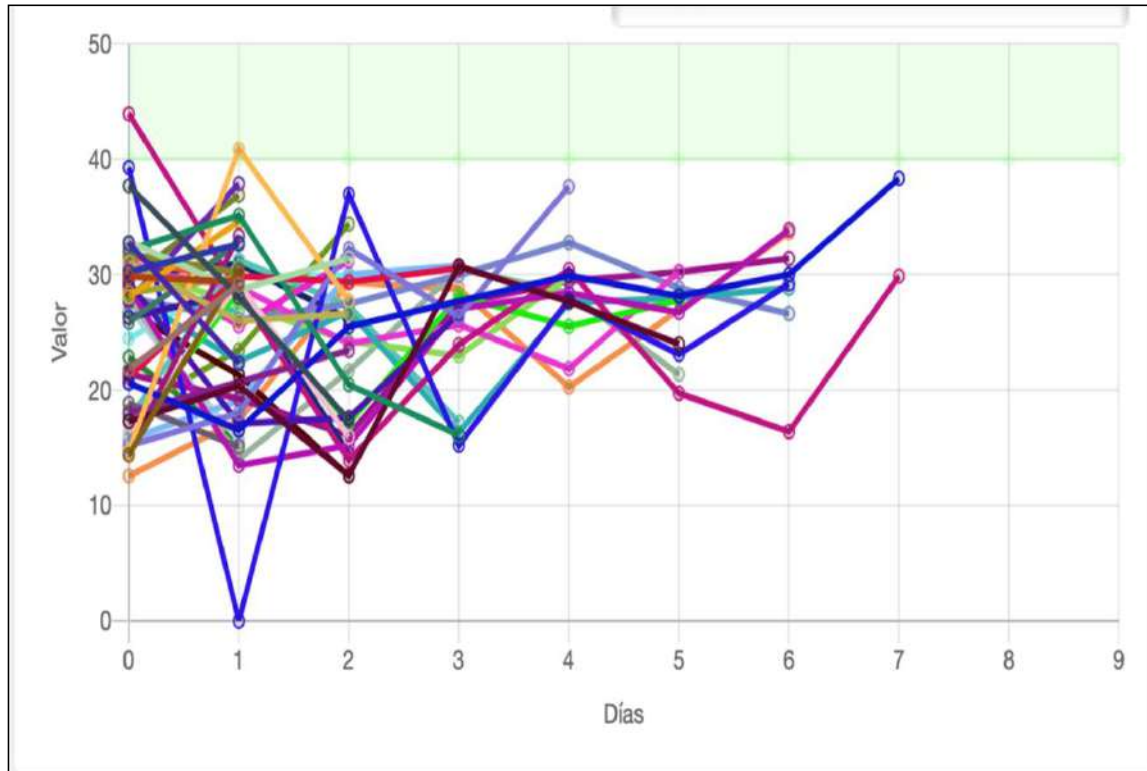
## Inclusion Criteria

- Individuals over the age of 18
- Both sexes
- Diagnosed with COVID-19 corroborated by PCR and CT less than 32 in gene E.
- To come to the service of Urgencias Adult a by symptomatology of COVID
- Voluntarily agree to participate in the study by signing the informed consent.
- With at least 1 symptom of the following: fever, headache, nausea, dyspnoea, myalgias, vomiting or diarrhea.
- With chest Rx without pneumonia criteria.
- Con  $SO_2 > 90$
- No history of allergic reaction

## Exclusion Criteria

- Diagnosis of cancer at any stage and of any kind.
- Decompensated comorities (Diabetes and ischemic heart disease)
- Patients with severe renal and hepatic impairment
- Immunocompromised patients
- Pregnant or nursing women.
- Participation in another clinical trial with an experimental drug in the last 30 days.
- Other pathologies that, in medical opinion, contraindicate participation in the study.

## Genes Confirmation Efficacy of WelBlo®



CT GENE-N CT GENE-E CT RdRP CI

Nov-21

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The PCR test on all patients was done by checking for three viral genes.



In WelBlo® group, only two patients were positive for six days (the maximum lapse of positivity).



Control group patients had an average of 21 days to tested negative for the SARS-CoV-2 virus.



One person was positive for 49 days in the control group.

# Genetic Variant Gene Confirmation

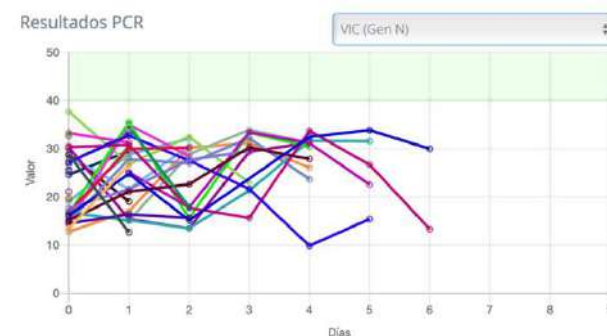
Graph A- FAM (RdRP)



Graph B- Texas Red (GenE)



Graph C – VIC (GenN)



Ct values of the three viral genes are shown as follows:

Graph A, analyzing the viral gene RdRP, most of the patients were negative after day two of treatment, only one person shown to be positive on day six.

Graph B, analyzing the viral gene E, the average to turn negative, is three days, only one person shown to be positive on day six.

Graph C, analyzing the viral gene N, the average of positivity, it is three days, only two patients shown positive infection on day six.

## Clinical Study Control

- **Monitoring:** Daily clinical improvement were evaluated for seven days of patient temperature , arterial oxygen saturation and other vital signs measurement.
- **Laboratory & Cabinets test :**First day of admission and on seventh day, blood samples were drawn to assess chemistry as per table

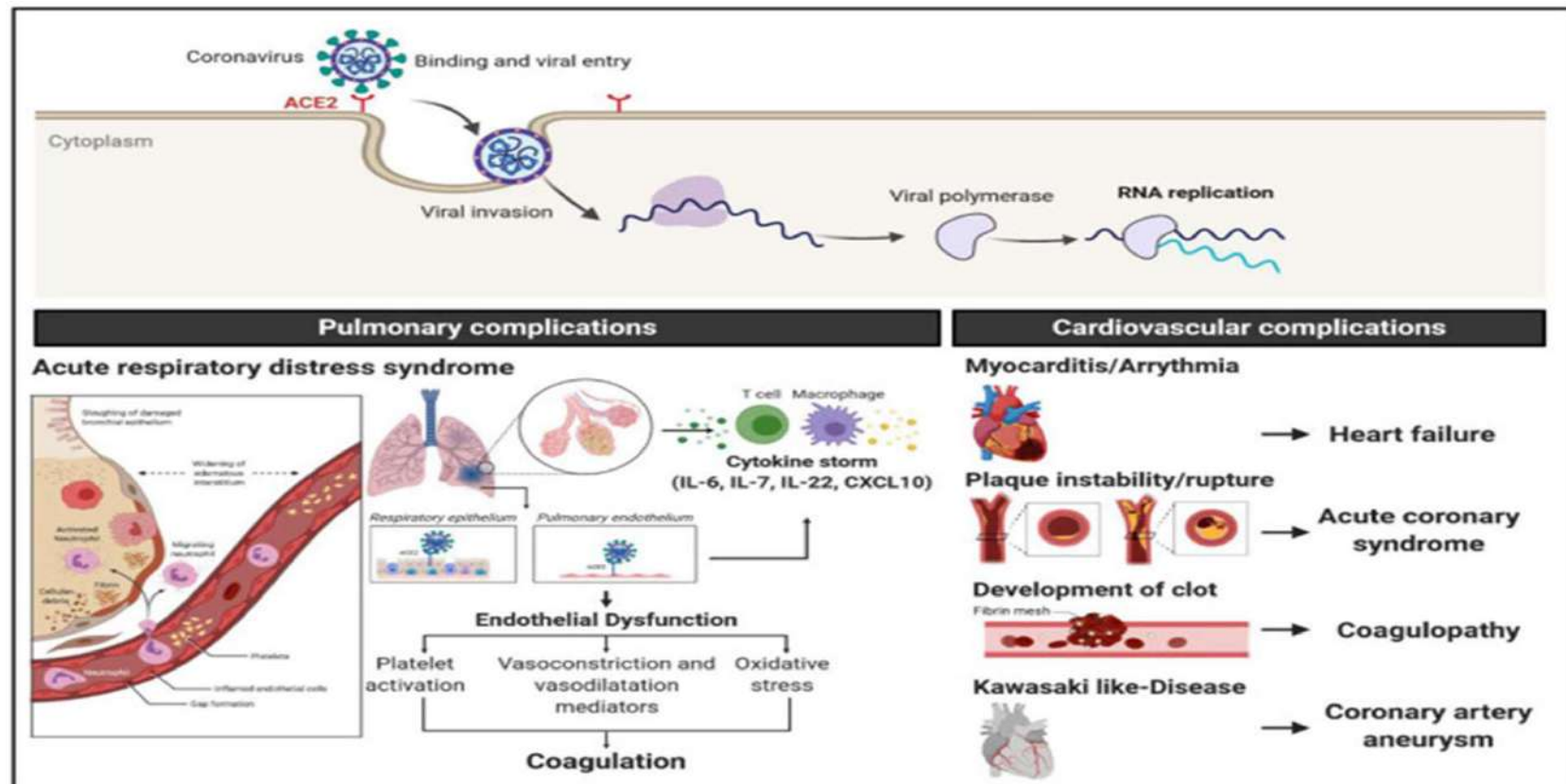
Immune Marker	Inflammation Marker	Haematological Studies	Radiological
G6PD	C- Reactive Protein	Complete Hematic Biometrics & Blood Chemistry	Chest – X ray
IgG	Globular Sedimentation Rate	Including Liver & Kidney Panel	NA
IgM	Pro – calcitonin	Pulse Oximetry	NA
NA	Ferritin Levels & IL -6	D - dimer	NA

- Daily **PCR Swabs** measuring cycle threshold (CT) were collected (period: 1 – 7 days)

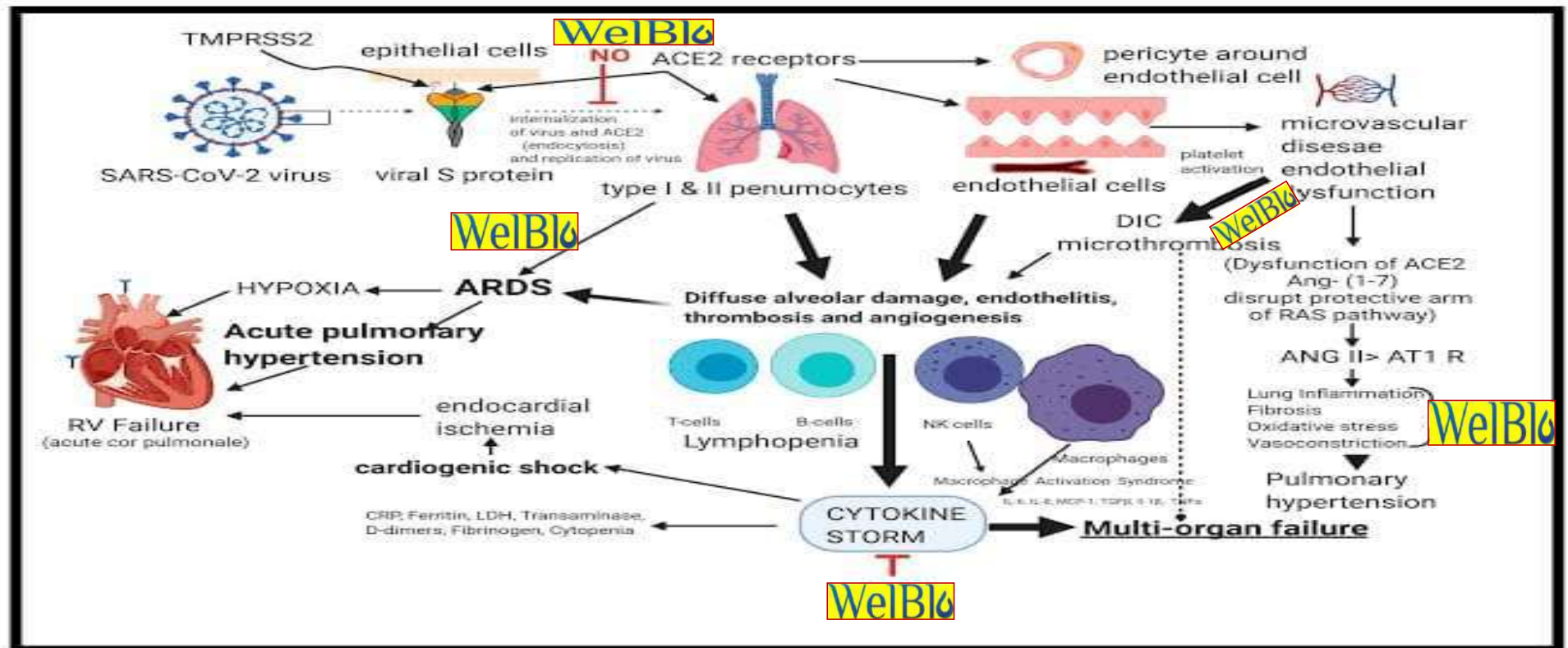
- **Outcome:** This study has shown that COVID positive patients who have undergone treatment using **Welblu** became COVID negative, after receiving just one to three daily doses. Patients that were positive for Covid-19 but not treated with **Welblu** showed an average of 3 weeks before achieving negative test results using regular treatment line.

# Scientific Rationale of WelBlo<sup>®</sup>

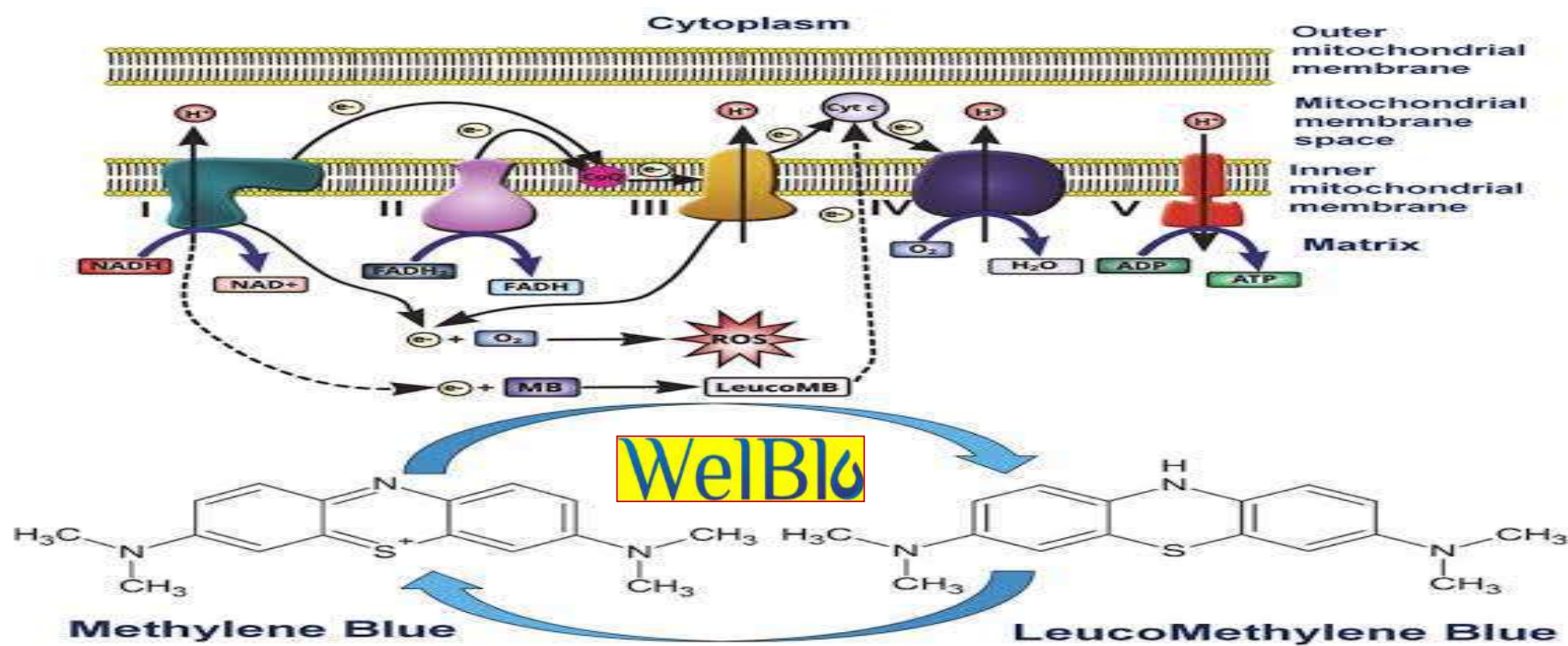
# Guest Covid -19 Entry and Impact in Human System



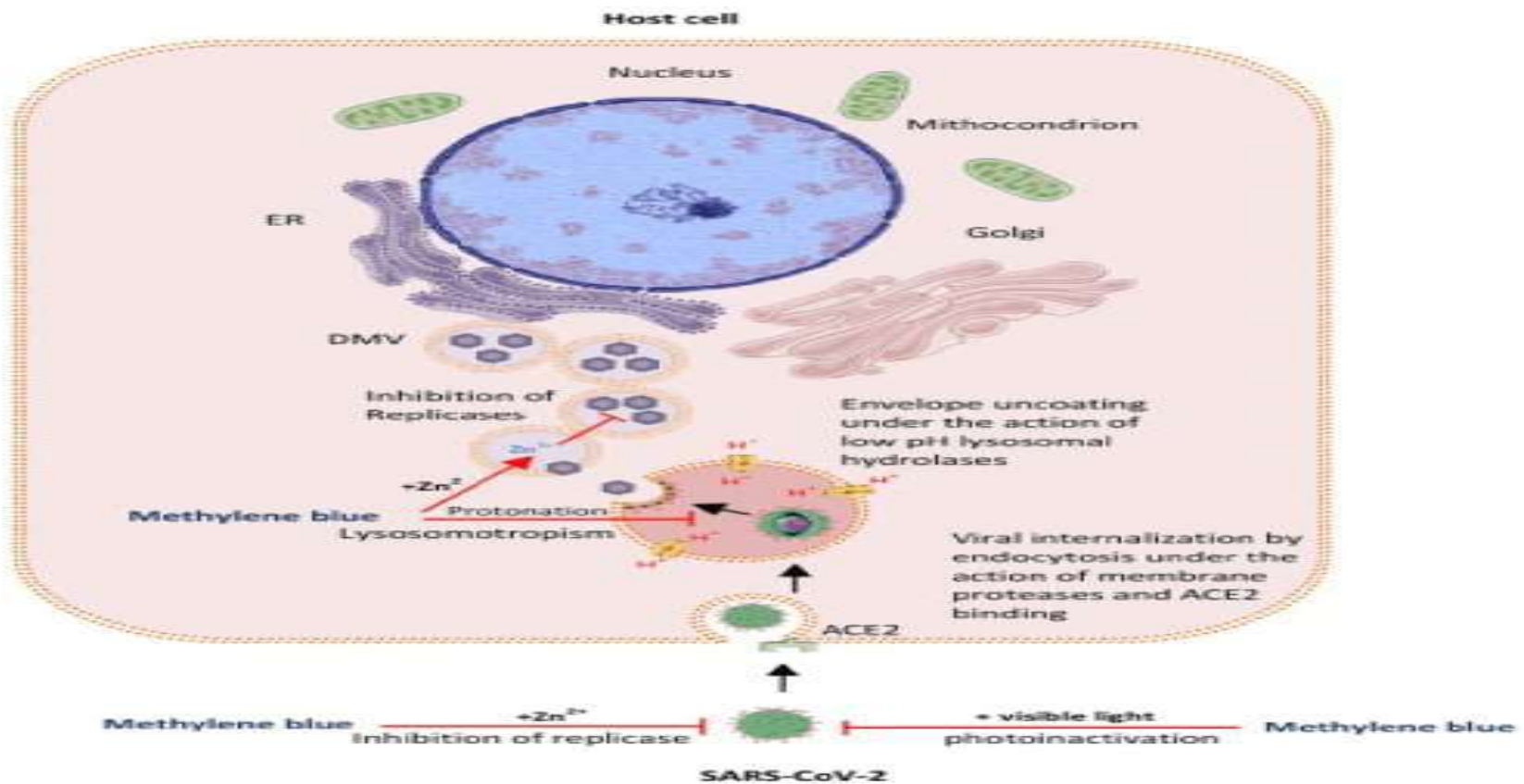
# Covid-19 Pathogenesis & WelBio® Action points in Cellular pathways



# WelBlo<sup>®</sup> - In-vivo Redox cycling Amplification

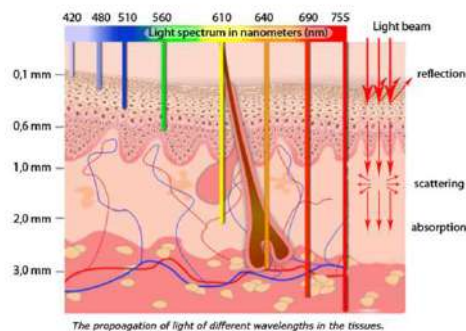


## WelBlo<sup>®</sup> – Host Infected Cell Impact

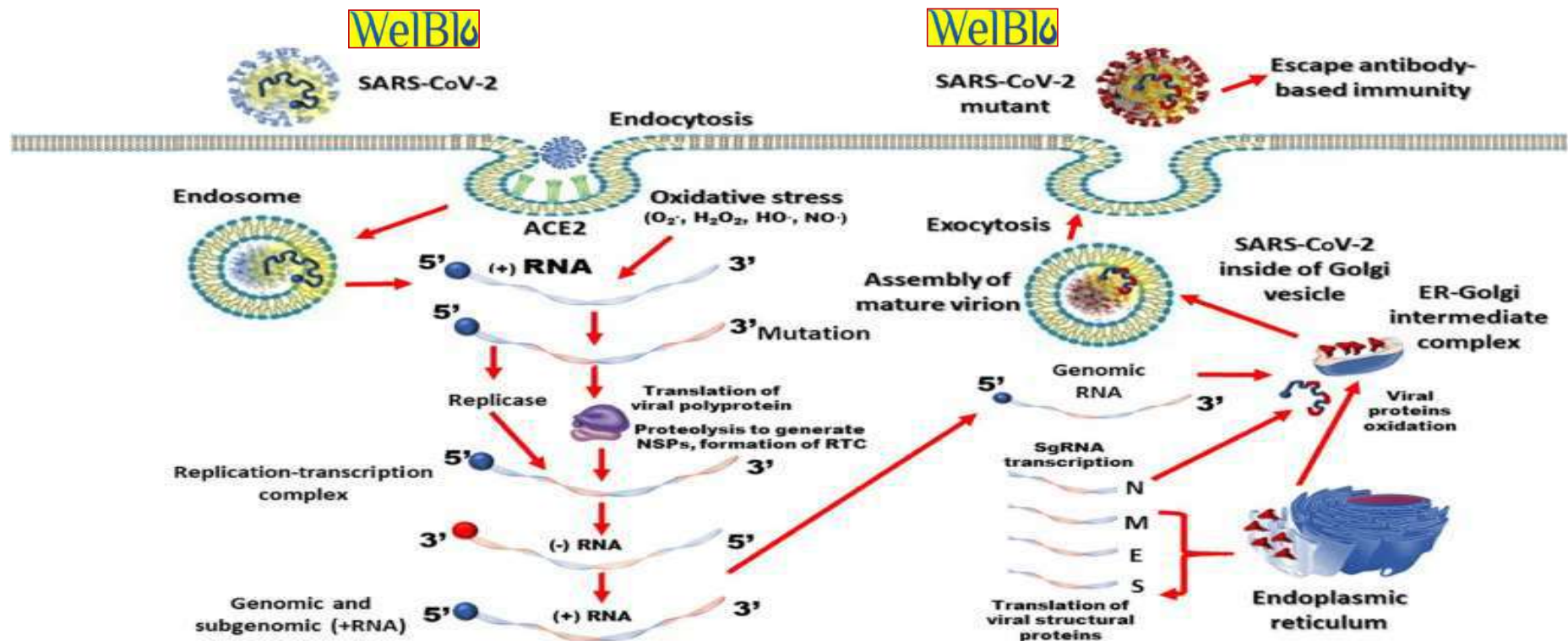


# COVID – Infected Patient System and Activated MB Action

- ❑ It acts just like oxygen in the mitochondria - accepts electrons at the electron transport chain (ETC) and increases ATP production.
- ❑ In situ, methylene blue is first converted to leucomethylene blue (LMB) via NADPH reductase. It is the LMB molecule which then reduces the ferric iron of metHb to the ferrous state of normal hemoglobin.
- ❑ In red blood cells, low dose MB changes the configuration of the iron [heme] in hemoglobin, the molecule in a red blood cell that carries oxygen. This improves the oxygen carrying capacity of hemoglobin which leads to increased ATP production from the ETC.

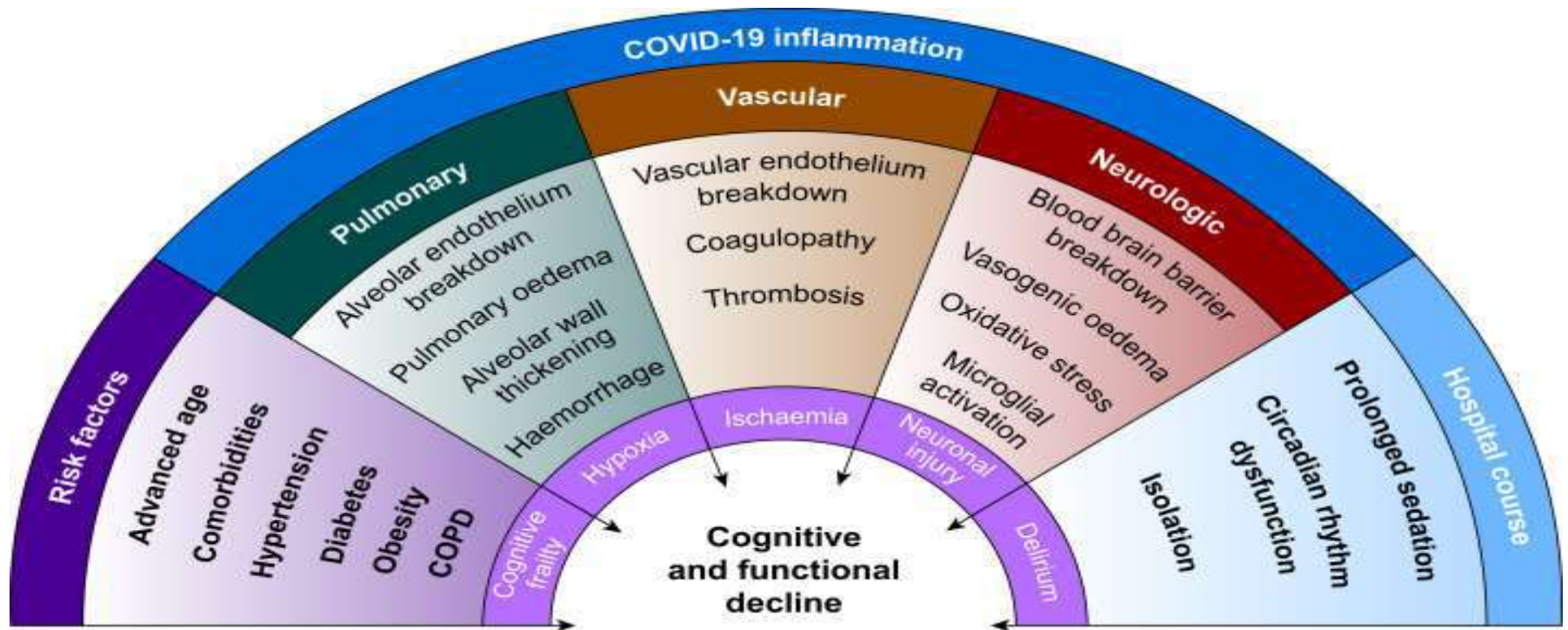


# Covid -19 Variant's Host Machinery cell Cycle



# WelBlo<sup>®</sup> Synergistic Action

## WelBlo<sup>®</sup> Improves



WelBlo®

## Synergistic Action



**METHYLENE BLUE**  
Ionic form

**PHOTODYNAMIC**  
Visible light



### Immunity & Wellbeing

Immunomodulatory, Anti-inflammatory, Pan-fungicidal & Pan-bactericidal



### Control

Alkalizing- Virucidal, Anti-coagulant, Prevent septic shock, Cytokine Storm



### Rejuvenation Support

Oxygen superoxide scavengers, Increased oxygen saturation



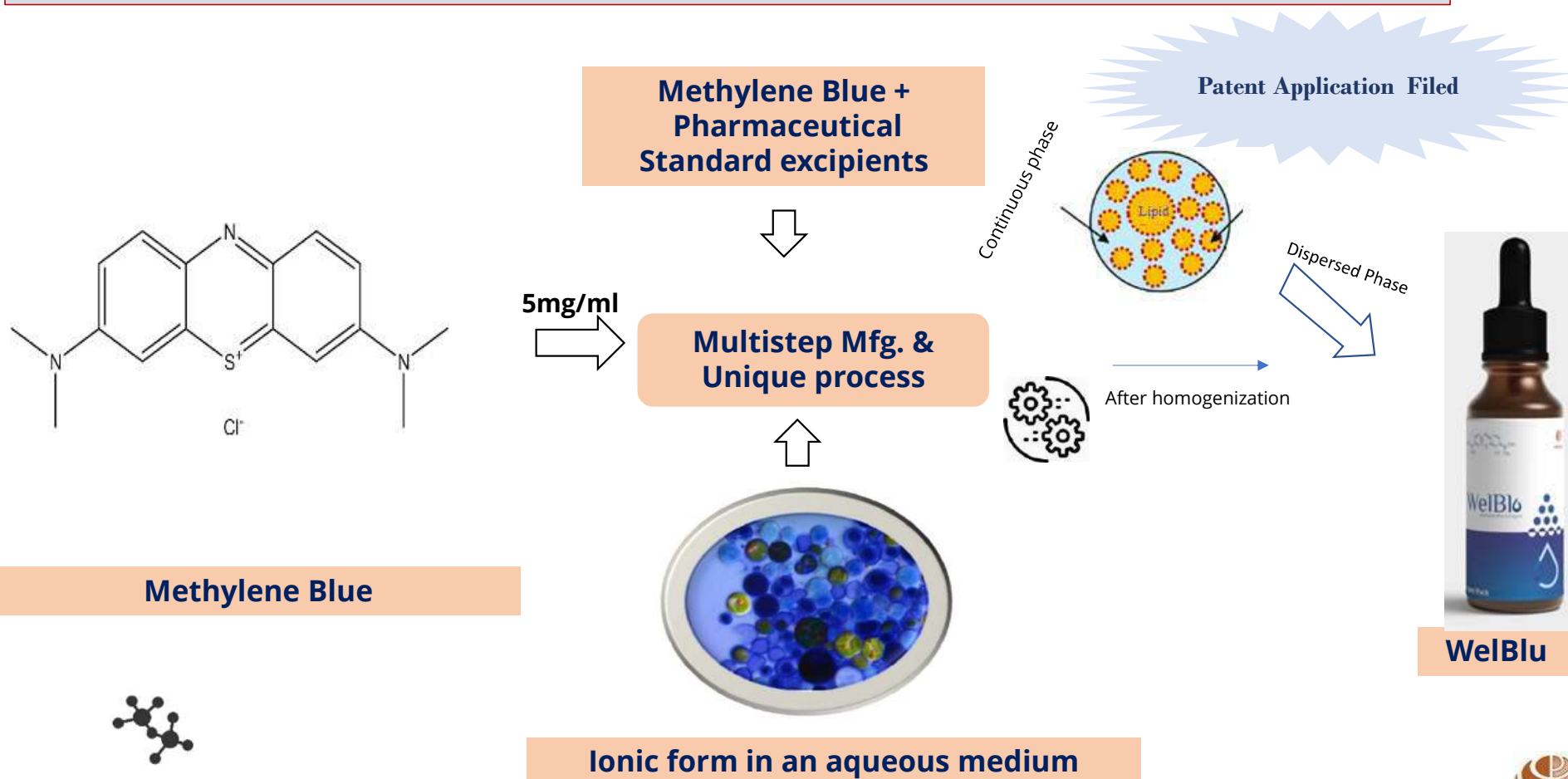
### Lifestyle Wellness Support

Anti depressant (serotonin analogue)



**Our product holds the promise of Covid control replication , structure and pathogenesis**

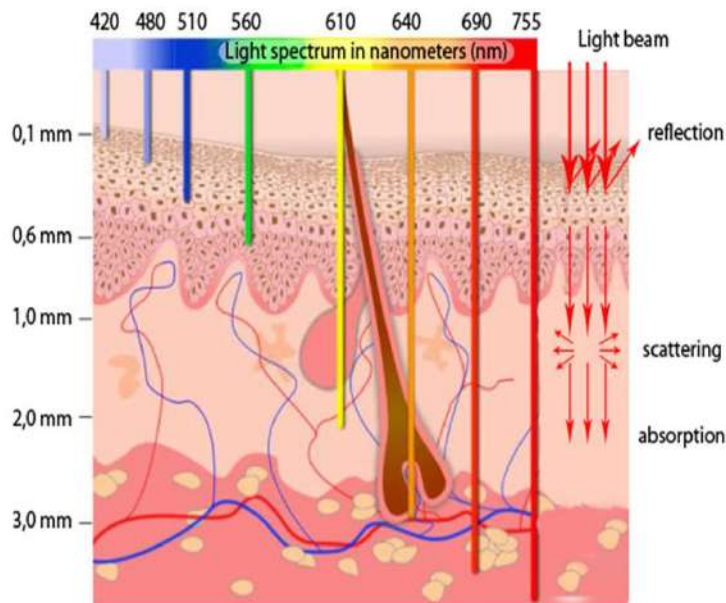
# WelBlo<sup>®</sup> Validated Patented Process – Drug Manufacturing



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## Validated Patented Process – Wristband Design



*The propagation of light of different wavelengths in the tissues.*

- Wristband device specifically designed with proper sequencing of LED light arrangements,
- Distance between the LED lights(both domed and non-domed), distance from the skin, nanometer wavelength, time of illumination and illumination power focused in directional light beams through the skin area to penetrate to the levels of therapeutic effect designed to increase of drug formulation molecule activity.

## Limitations

1. Renal failure Treatment.
2. Dose Dependent Toxicity ( $>7\text{mg/kg}$ ) with Nausea, vomiting, hemolysis.
3. Contraindicated in Certain Population in Taking serotonin inhibitors & in person with G6PD Deficient (Glucose 6 Phosphate Dehydrogenase deficiency).
4. Hypersensitivity.
5. Pediatric Age Group – Study under Trails
6. Pregnancy (Exclusion criteria: Clinical.gov)

## WelBio® Conclusions & Treatment Outlook Going Forward

1. Irrespective antibody level post vaccination infection Management
2. Will work effectively on Coronavirus strains -Alpha, Beta, Delta, Delta+, Gamma variations
3. Will help in preventing spreading community transmission in third wave and prevent individual from dreadful ICU admission.
4. Bridge gap between vaccinated & non-vaccinated group.
5. Trial on Pediatric age group is underway, data should help address pediatric populations too
6. Lessen the Health economic burden of our country on a huge scale.
7. Create an eco-system of innovation, making country proud, and lead to several innovation offsets.



**Focelite 's Smart Innovation Product for Covid 19  
Request filed for emergency use authorization to  
help Patients globally.**

# About

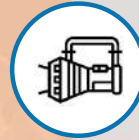


FOCELITE

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Focelite - technology innovation Platform Company



**WeiBio<sup>®</sup>** : First amongst our portfolio of products



A team of innovative diversified minds with a goal of integrated approach



Focelite innovation teams are spread across Singapore, Australia, India and America



Patent filed and clinically tested



Bangalore Bio innovation center Incubatee

# Our Partnership Plans

## Focelite

### Innovation

Design new product concepts, Patent filings

### Clinical Evidence

Design & conduct clinical trials to generate evidence for claims

### Manufacturing & Supply

Clinical/commercial manufacturing supply chain management

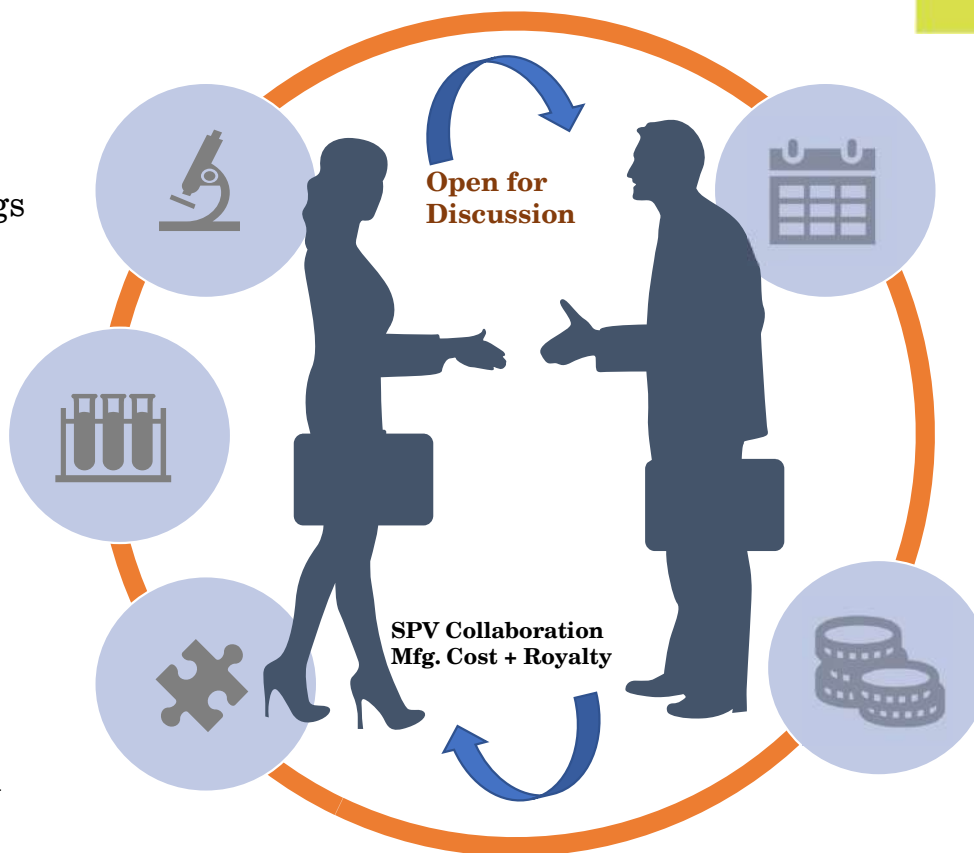
## Our Partner

### Regulatory

Regulatory filings and marketing authorizations

### Commercialization

Pricing, Market access, Branding, Promotion & sales, Customer relationship management



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# FOCELITE

## Thank You



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