



CDMOs an essential part of the value chain.

www.escoaster.com | www.escovaccixcell.com

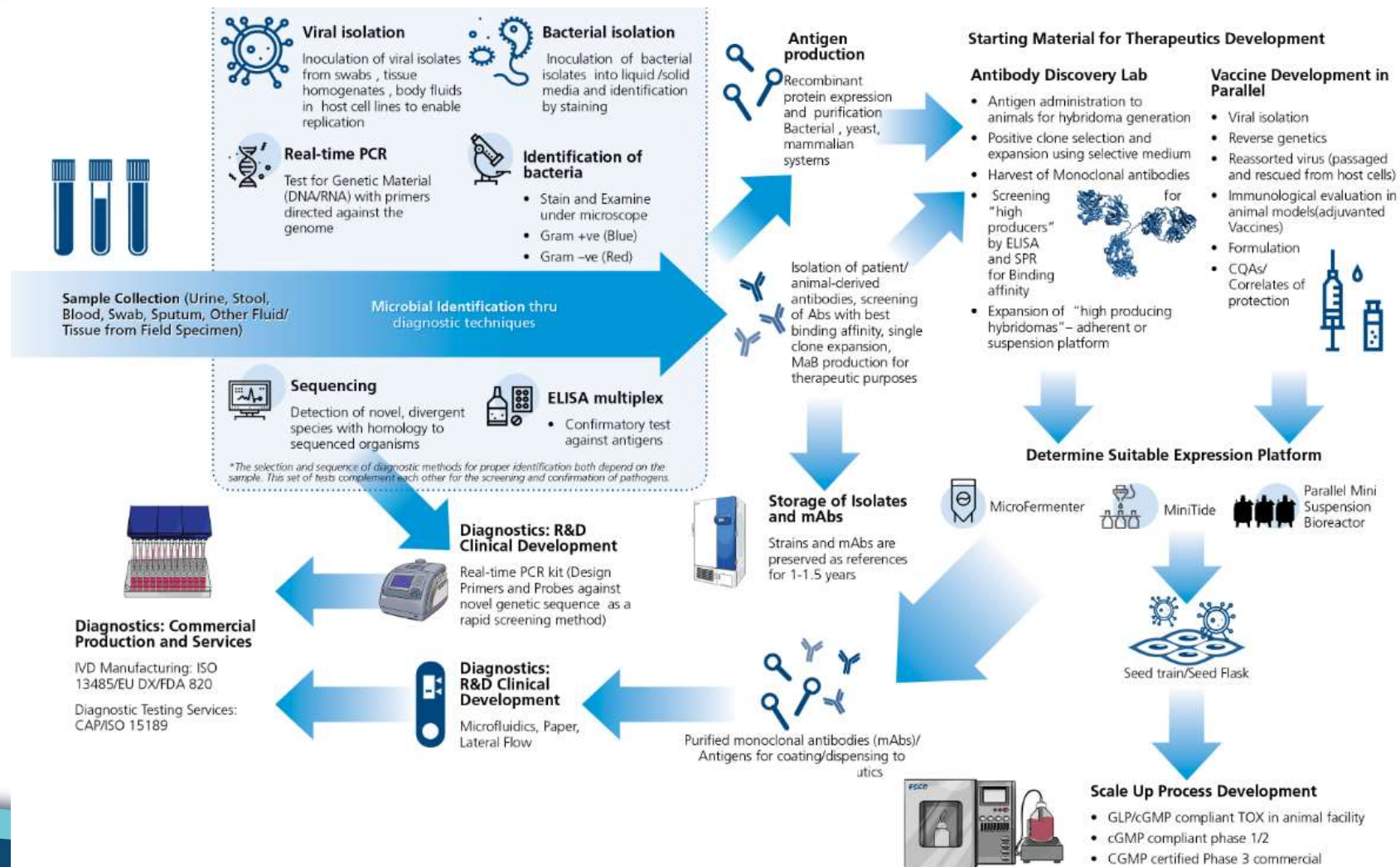


Created by: <XL Lin>
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Disclaimer

- As Covid-19 is rapidly evolving daily, information presented is accurate as of this date.
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- The presentation provides an overview of the subject and does not intend to be complete in every detail and in all options.
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Role of CDMOs from CRO, Dx, Vaccines and Therapeutics



E.G of MDX When to boost. (Beyond vaccine self sufficiency)
Kit Components for imTracker COVID-19

GEN-Y imTracker COVID-19^{2.0}



Kit components



Wuhan wild type,
UK B.1.1.7,
South Africa B.1.351,
California B.1.427/429,
Indian B.1.617.1,
Indian B.1.617.2



Negative control reagent



Quality control reagent



ACE2-Peroxidase
(dark vial)

Generic lab consumables for ELISA



buffer
(PBS)



ELISA
washing
buffer
(PBS-T)



ELISA
blocking
buffer
(BSA in PBS-T)

96-well microtitre
plate

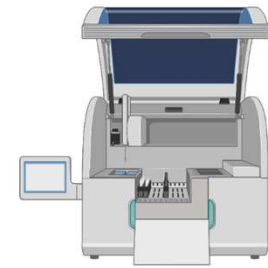


TMB
substrate



Stop solution

Generic lab
equipment for
ELISA



ELISA plate washer

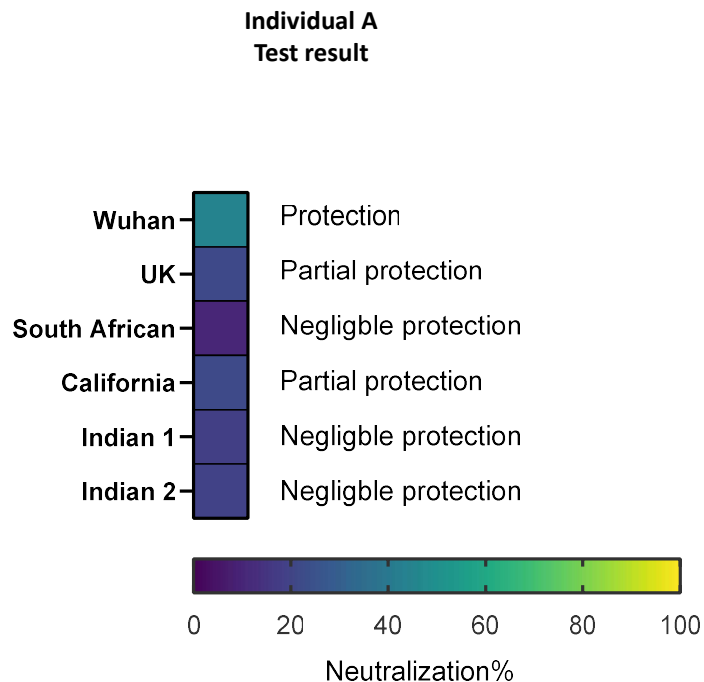


ELISA reader

ELISA Plate Format

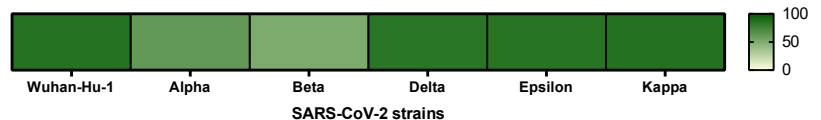
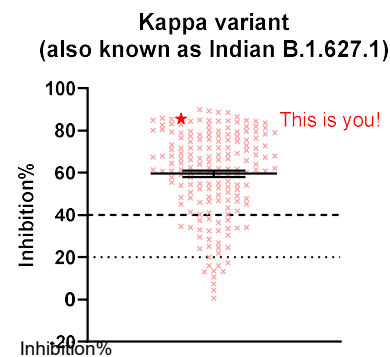
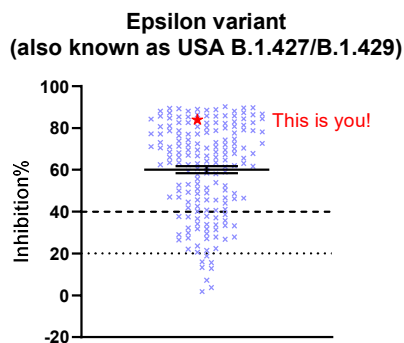
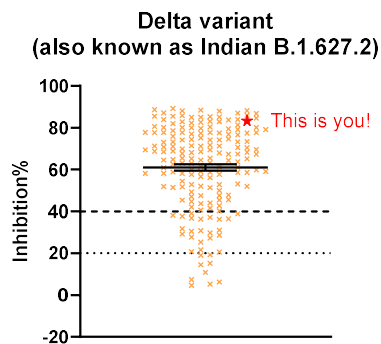
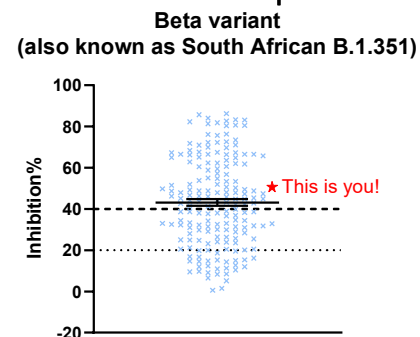
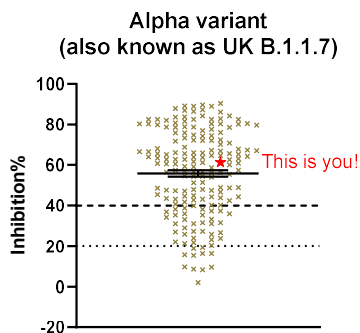
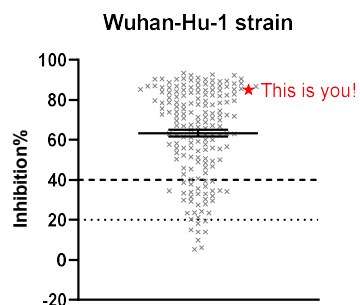
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imTracker MULTI Provides Broader Deeper Insights



- Colour coding identifies an individual's personal antibody neutralizing ability versus the most concerning viral variants
- For example, from the read out;
 - Yellow color means there is good neutralizing antibody protection whereas dark blue indicates levels that may be below the threshold of protection or have no protection leading to reinfection with that variant
 - The evolution of the neutralizing antibody capability in these patients can be tracked further with repeated tests – say 3/6/9 months following the 2nd vaccine dose
 - By understanding the current status of an individual's neutralizing antibodies against multiple viral variants, this will enable the ability to:
 - Track Travel Appropriateness
 - Track Vaccine Effectiveness
 - Track Booster Requirement
 - Track Vaccination Status at Border for Entry
 - Track Data on Immunity against Multiple Variants
 - Track Data Differences in Groups; by gender, blood type, ethnicity, age ...

Gen-Y imTracker MULTI for Covid-19 – Sample Test Result



Virus Strain	Wuhan	alpha	beta	delta	epsilon	kappa
Neutralization %	84.3	59.2	46.4	82.5	85.0	82.1

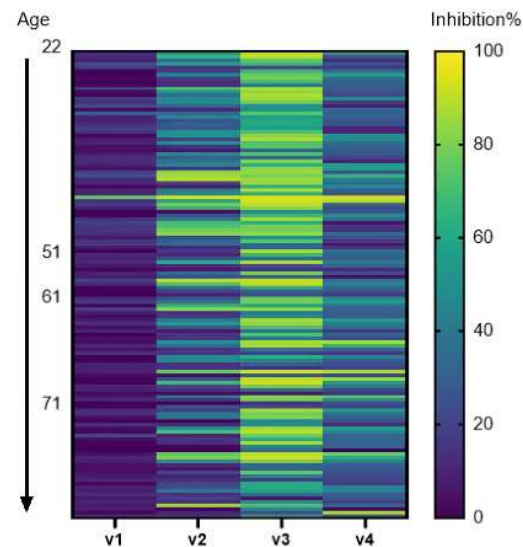
Over 40% = Good neutralization

20-40% =Weak Neutralization

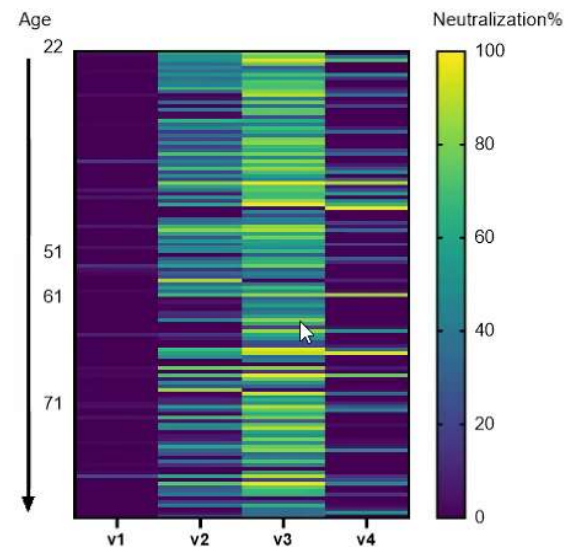
Under 20% = No Neutralization

Population Cohort Studies.

ACE2 inhibition ELISA
(Wuhan-Hu-1 RBD) by Age



pVNT by Age



Please note that this is only a preliminary result. Some data are affected by outliers in triplicates so there will be some changes. Some samples became very neutralizing at v4. Suspected infection after v3. Need to check anti-NC antibody titer at v4.

CDMOs Enabling Companies to Overcome Valley of Death in Commercialization

ESCO
LIFE SCIENCES

Basic and pre cGMP Translation Tools

ESCO
ASTER

Esco Aster bridging non GMP lab processes into GLP/cGMP. Process development of bench scale into cGMP scale for CMC package leading to IND Phase 1 and 2. CRO work to enable scale up.

ESCO
Healthcare "Discovery to Delivery"

Phase 3/ Commercial is either continued on by Esco Aster Commercial Sites or tech transfer into client own site built by Esco

Phase 4

Also known as post market surveillance, e.g. Safety for up to 10 years post gene therapy.

Highest Yield
Affordable Cost
Linearly Scalable
Quality by Design
FTO

Phase 2
Safety, Efficacy
Clinical Cohort
larger number

Phase 3
Safety, Efficacy Clinical
Cohort largest number
/ Challenge study (if
applicable e.g. Flu
Vaccine). Process
locked in and will not
change.

Commercial

Phase 1
Safety Clinical Cohort
small number

File IND with
CMC

GLP Tox Non Human
Primate or Large
animals (Rabbit, Pig)
GLP Material.

Process Valley of Death 1
Lab-GLP/GMP

- Identify Critical Quality attributes
- Process Analytical Techniques
- Identify cGMP Assays and Analytical Methods to guide and inform cGMP PD

Process Valley of Death 2
Lab-GLP/GMP

- GMP to full cGMP
- In some instances processes that work in phase 2 are not repeatable or consistent when scaling up into Phase 3 / Commercial

Process Valley of Death 3
Commercialization roll out

- Lack of reimbursement
- Anti-movements (e.g. Anti Vaxxers)
- Lack of public awareness
- Slow introduction into NHIP or approval by regulatory (e.g. biosimilars)
- Lack of infrastructure (e.g. Central Diagnostic Labs or ICUs for Car T, autologous facilities), viral vector shortage globally, etc

Preclinical
Development



**Final Animal
Model**

Translational
Research



POC in Mice

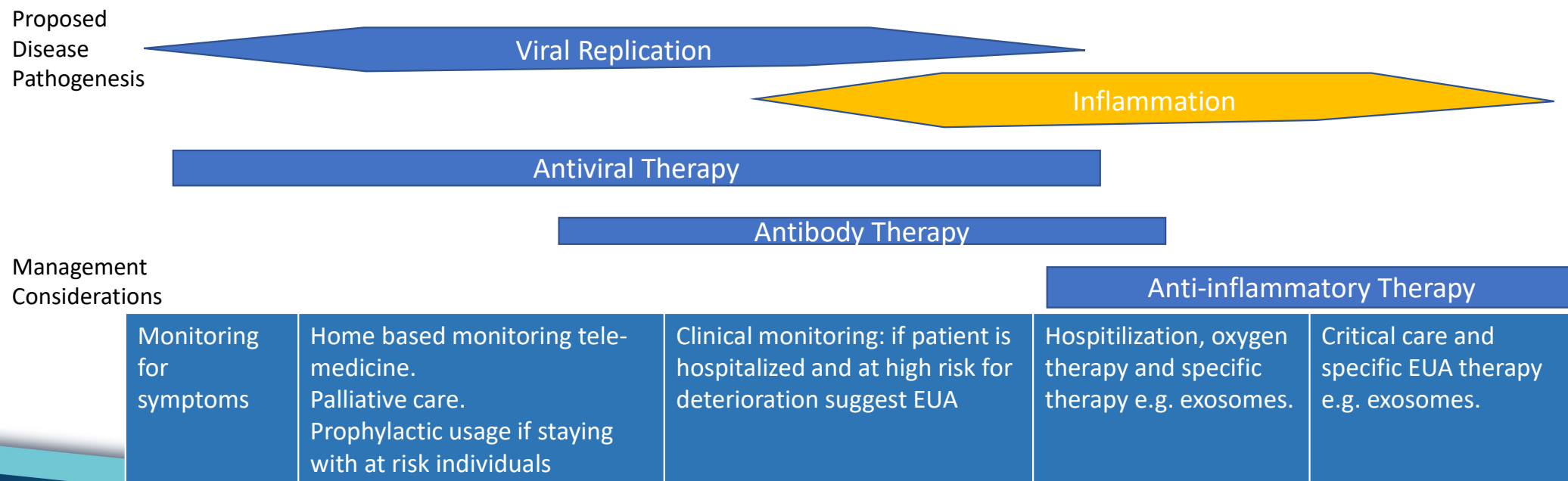
Basic
Research



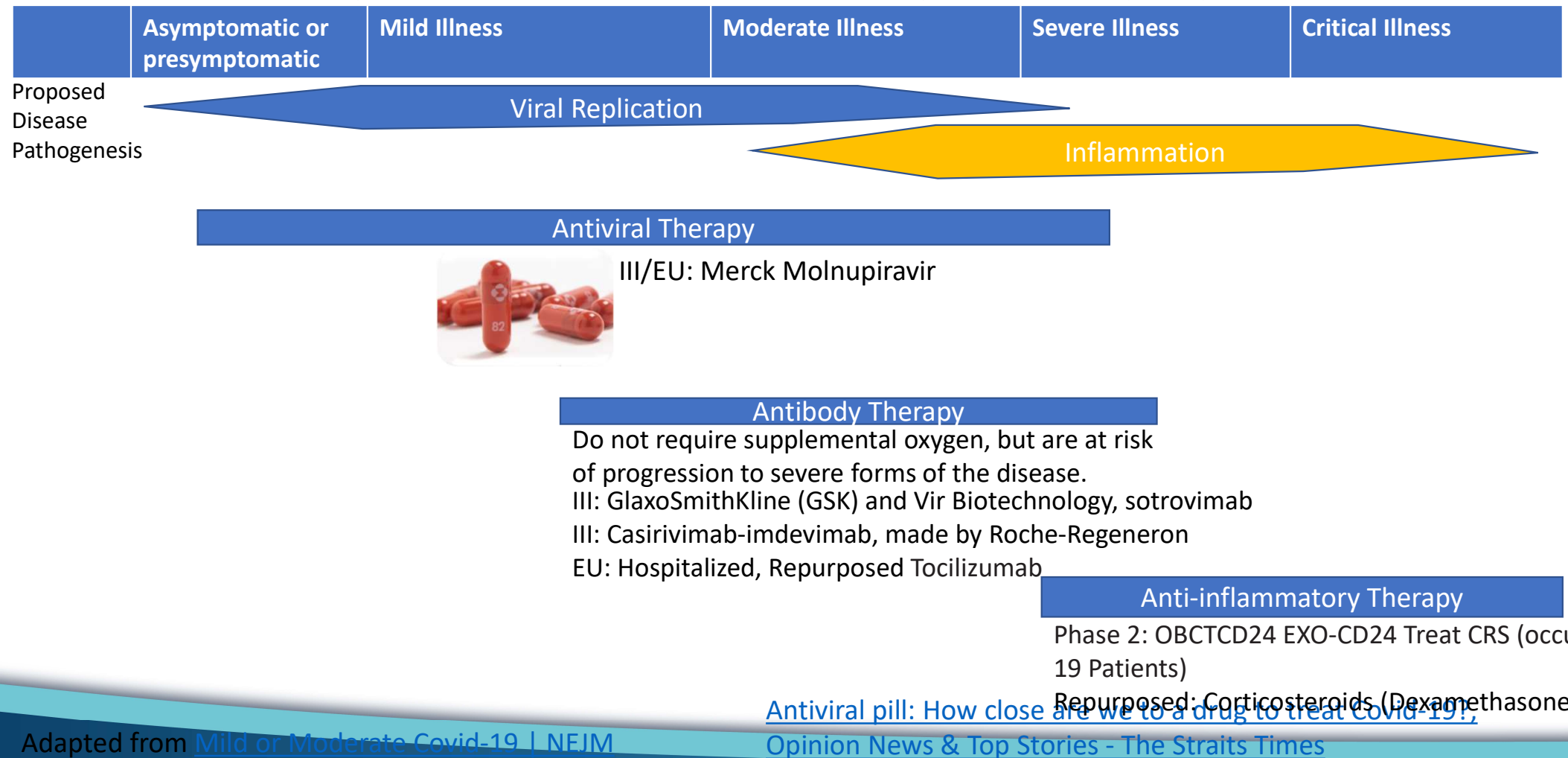
Early Stage
Discovery

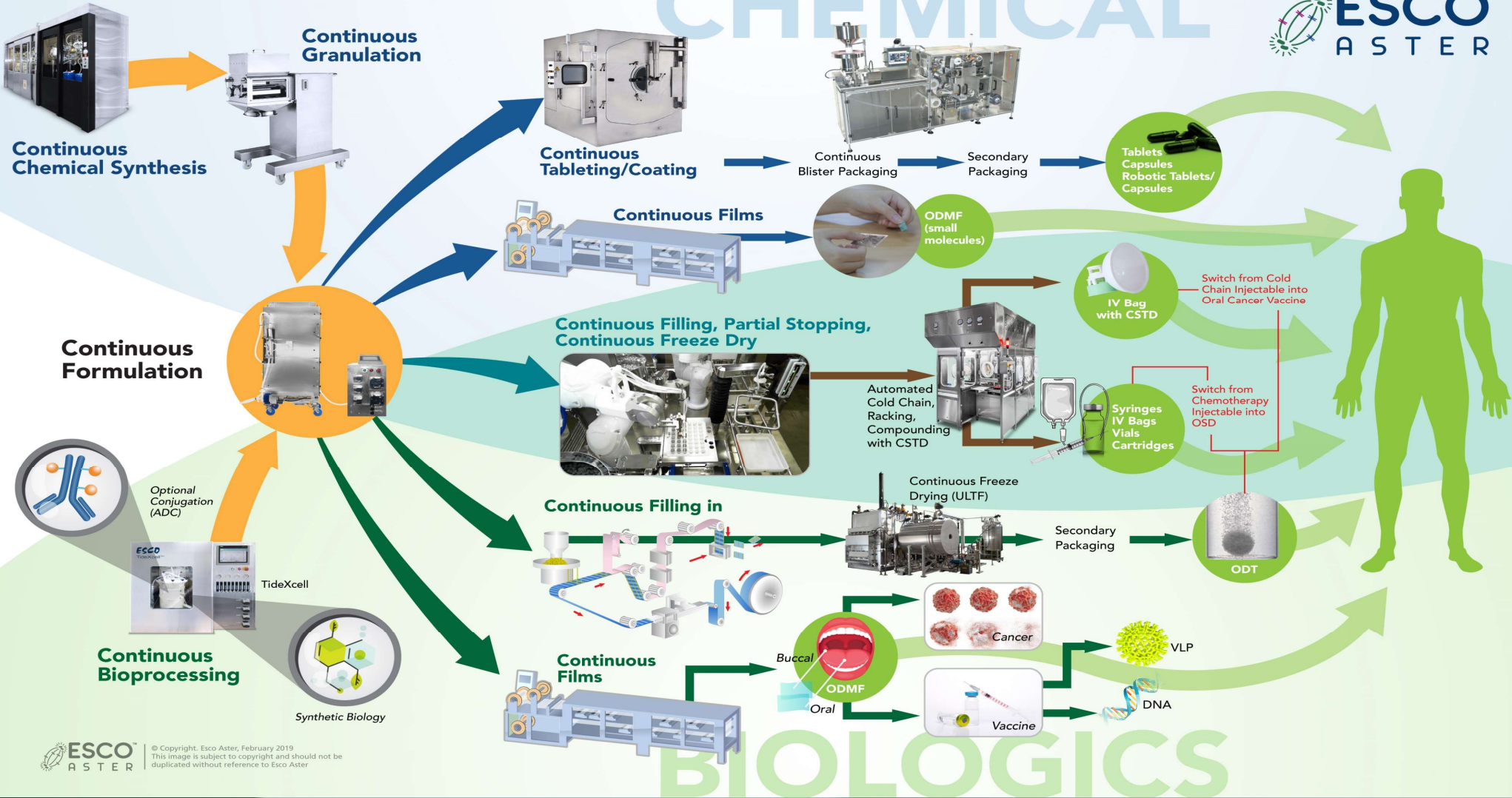
Current Landscape and use cases of Covid-19 Therapies

	Asymptomatic or presymptomatic	Mild Illness	Moderate Illness	Severe Illness	Critical Illness
Features	Positive SARS-COV-2 test; no symptoms	Mild symptoms (e.g. fever, cough or change in taste or smell no dyspnea)	Clinical or radiographic evidence of lower respiratory tract disease; oxygen saturation $\geq 94\%$	Oxygen Saturation $< 94\%$ respiratory rate ≥ 30 breathes / min lung infiltrates $> 50\%$	Respiratory failure, shock, and multiorgan dysfunction of failure

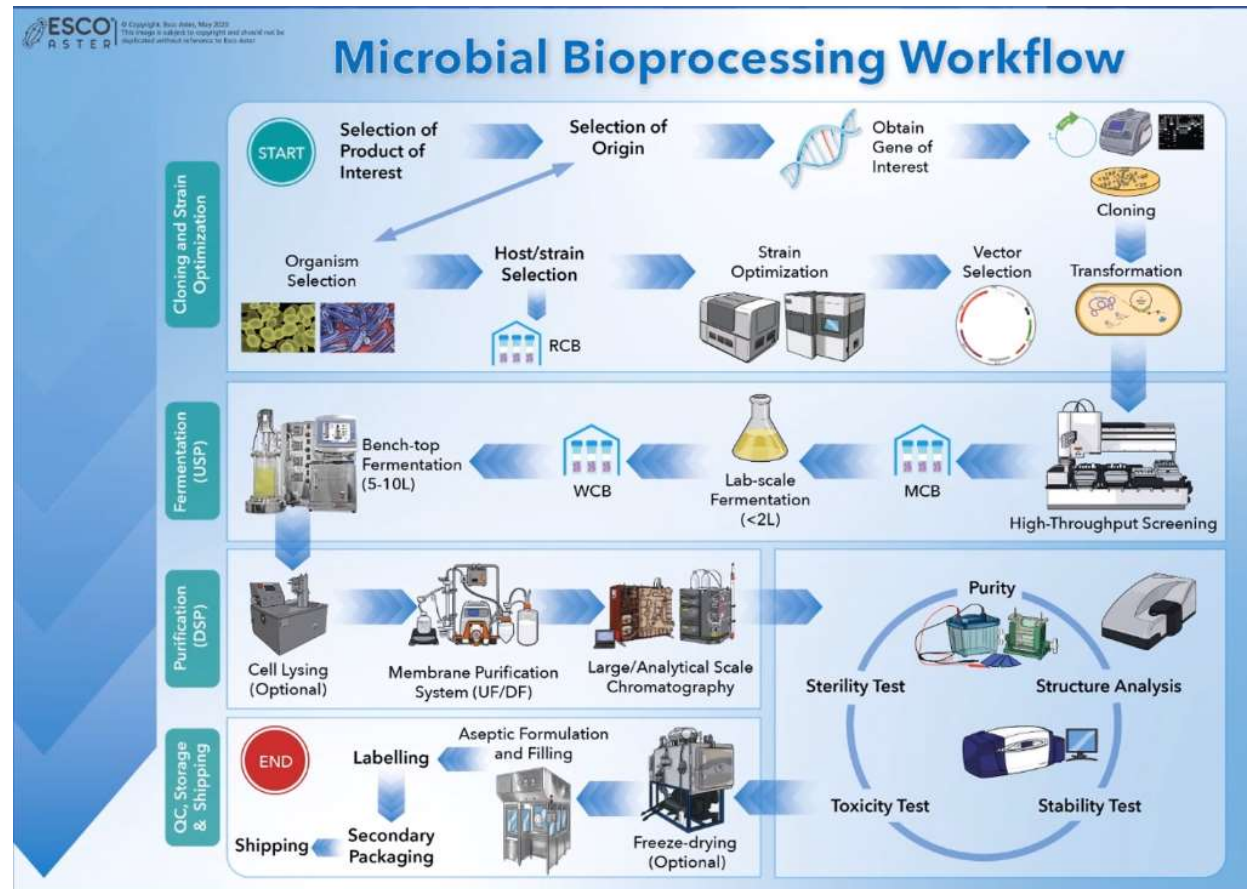


Current Landscape and use cases of Covid-19 Therapies including stage of clinical trials





Esco Aster Microbial Process for LMIC Open-Source Vaccines e.g. RBD219-N1C1



New operational paradigm from traditional CDMO to DBOT?

Esco Aster Single Use Suspension Mabs Generic Production



**Cryovial Hek 293 or CHO
MCB/WCB
(Thermo or Merck or
Canada)**



**T-75
(TBC)**

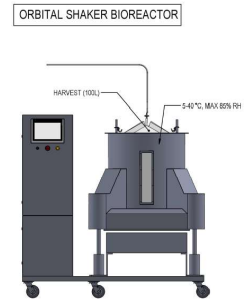


Seed Train

Filtration



**Suspension Bioreactor perfusion
single use up to 6,000L**



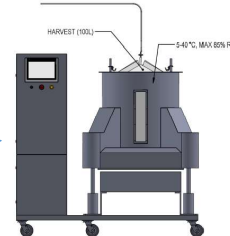
Harvest+Filtration



**TFDF or
Single Use continuous centrifuge**



**3 step
Chromatography**



**Final Filtration,
Formulation
& Filling in DS Bag.**



**Freeze -60
TBD if CRF or BF.**

Esco Aster Single Use Adherent Vero Virus/Oncolytic Virus/Viral Vector Production



**Cryovial
Adherent Vero
Cells:MCB/WCB.**



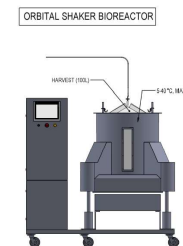
T-175



**CelCradle X Vero
Seed Cell with automated
harvesting**



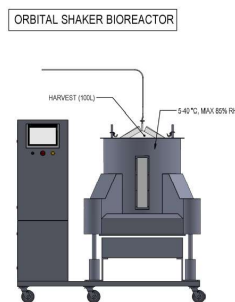
TideXcell Vero+Infection



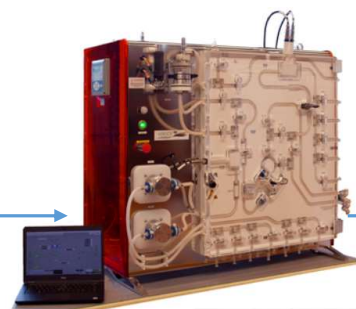
Harvest Virus



**TFDF/TFF or
Single Use continuous centrifuge**



DNA Digest Benzonase



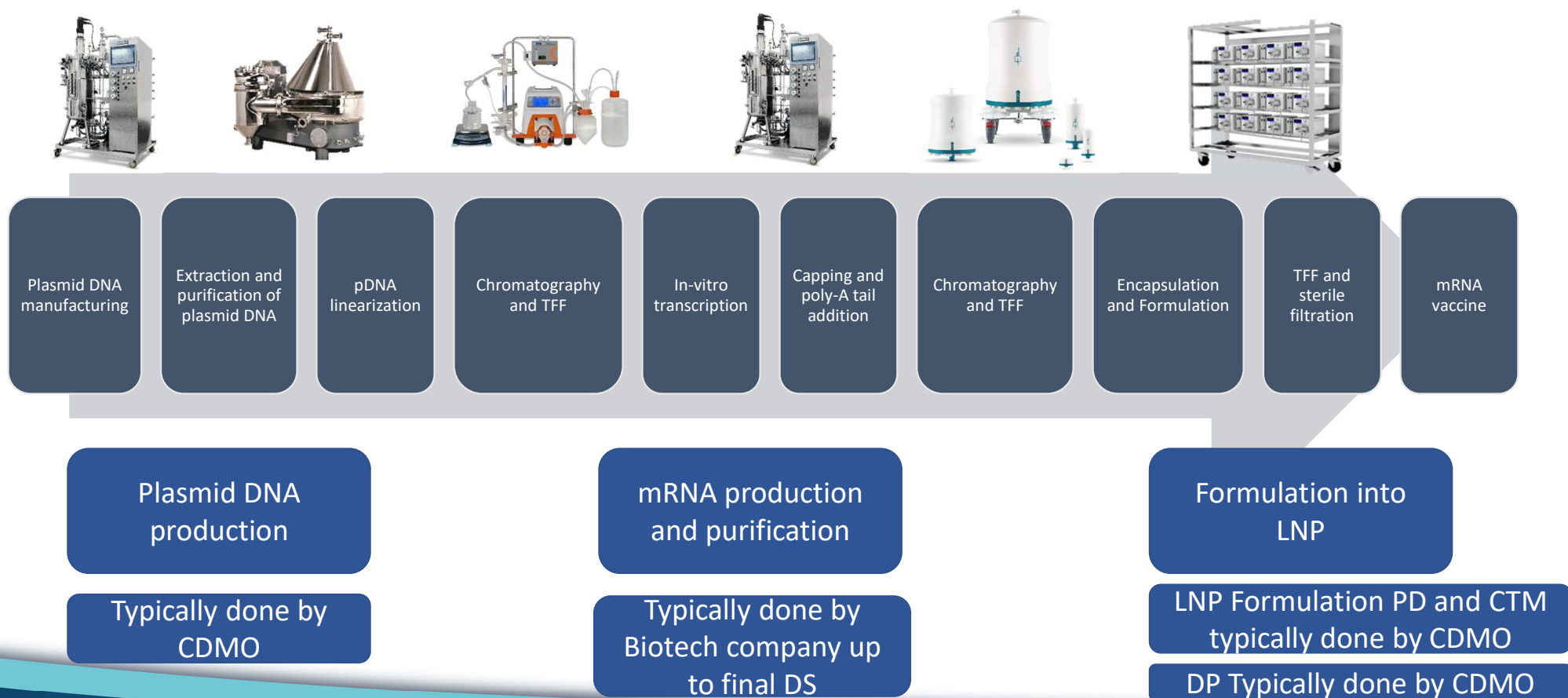
**One step ion exchange
Chromatography
SO3 or Precipitation**



**Formulation
0.2µ Filtration
& Filling in Glass or COP
vial.**

**Freeze -60 or
thermostable
TBD if CRF or BF.**

mRNA/LNP Vaccines



PROVAXUS COVID-19

Preparing for future COVID-19 variants and the need for booster shots against these variants



Developing novel mRNA vaccine



Fraction of the cost of current vaccines, less than US\$10 per dose



Planned deployment 2023



Optimized for wide range of variants

Provaxus Vaccine Advantages: High-Tech Low-Cost



**mRNA vaccines
are proven to be
highly effective**



**Lower price point
compared to other
mRNA vaccines**



**Improves
safety**



**Removal of ultra-low
temperature cold
chain**

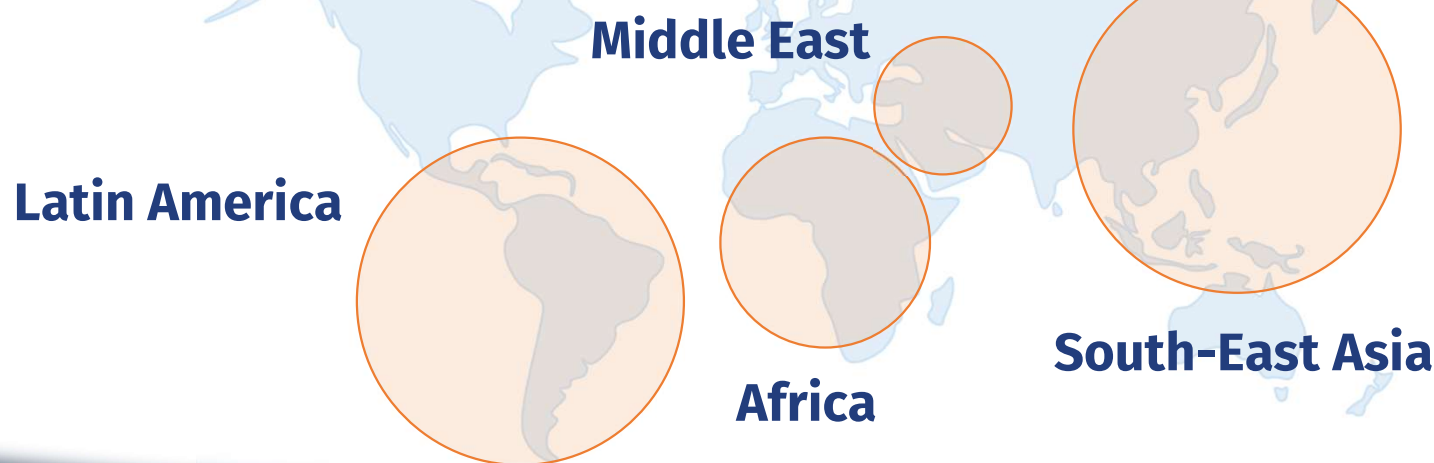


**Local
Manufacturing**

CONFIDENTIAL

Early target markets for Provacus Vaccines

Cost-enabled Provacus vaccines are designed with the intent to provide access to superior vaccine technology to the world's most vulnerable and underserved populations.

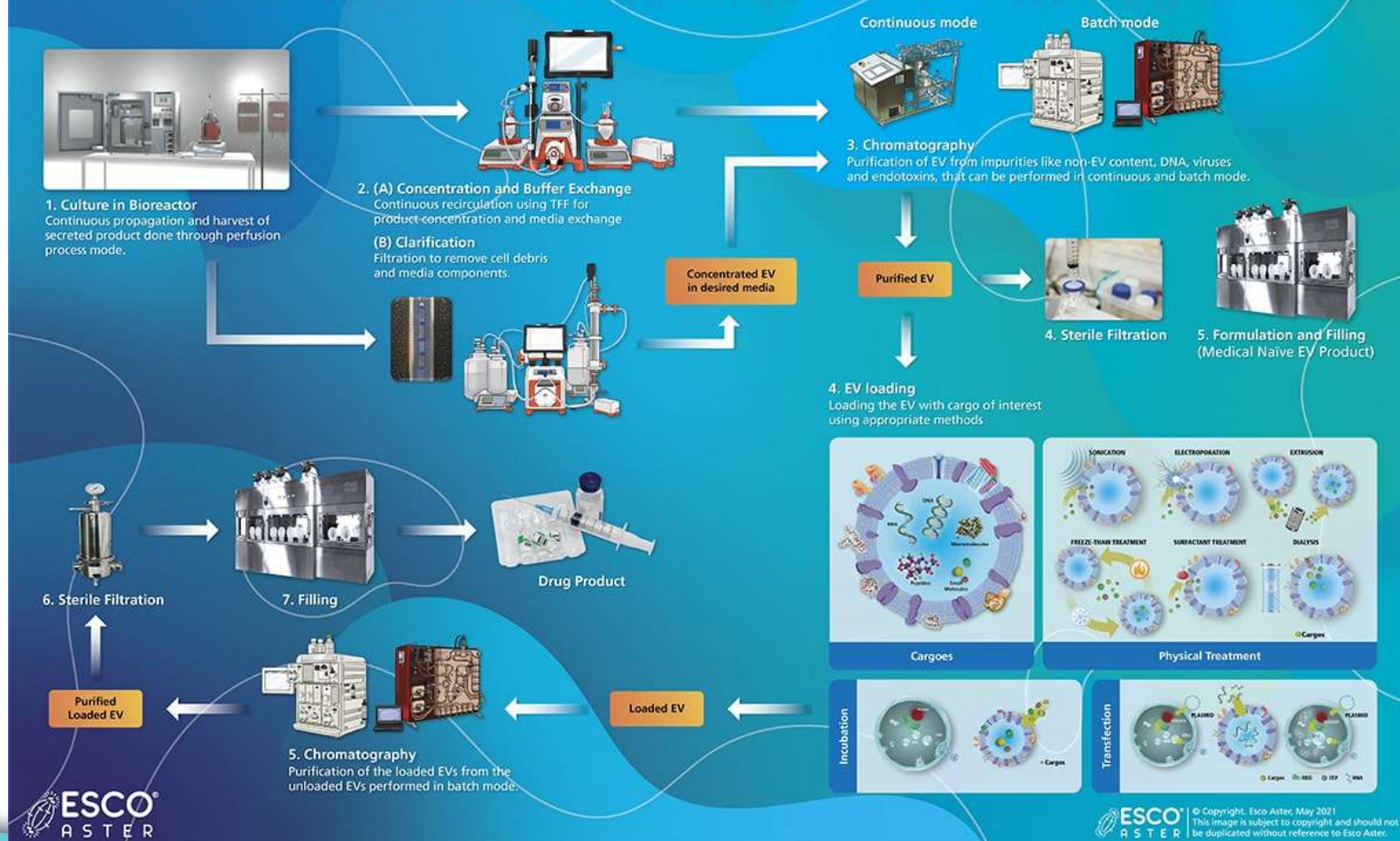


COVAX



BILL &
MELINDA
GATES
foundation

Overall Exosome Manufacturing Workflow



CDMOs play an important role in vaccine self sufficiency.

- Esco Aster has variety of mfg platforms and partners to help in early stage development and tech transfer from CDMO model to DBOT model.
 - Fermentation of sub-unit vaccines (Gen-Y)
 - Adherent VERO for LAIV/LAV (Vivaldi Biosciences)
 - Suspension for Covid-19 Mabs for Dx Antigens and Therapeutics (Gen-Y)
 - mRNA-LNP platform (Provaxus)
- Esco Aster is the only life sciences company that is neutral and operates within African continent for African from our base in South Africa.
- We are here to support you in your vaccine self sufficiency journey from tools, technologies, platforms, human resources, training.
- Contact us to collaborate!





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