Batavia Biosciences

Accelerate Biotechnology

Center of Excellence CDMO for Biopharmaceuticals

BATAVIA biosciences

Rapid response, low-cost manufacturing of viral vaccines against emerging infectious disease threats

Alfred Luitjens
DCVMN
29 June 2023

BATAVIA biosciences

Batavia: A CDMO with Global Presence

Batavia Staff

- 45% PhD, 30% MSc
- 120 FTE Netherlands
- 35 FTE Woburn

Batavia Biosciences

A part of CJ Corporation since Dec 2021

- Food & Food Service
- Biotechnology
- Logistics & Retail
- Entertainment & media

CJ R&D center Blossom Park in Gwanggyo (Total Floor Area: 109,922m²)

Annual revenues(’22):	±30 Billion USD
Annual profit(’22):	±1.6 Billion USD
No of employees:	±50.000
Geography:	Global

Vaccine inequality against existing diseases remains

81% Global vaccine coverage dropped during COVID pandemic to 81%

29m 29m children under 1 yr of age did not receive basic vaccines, highest since 2009

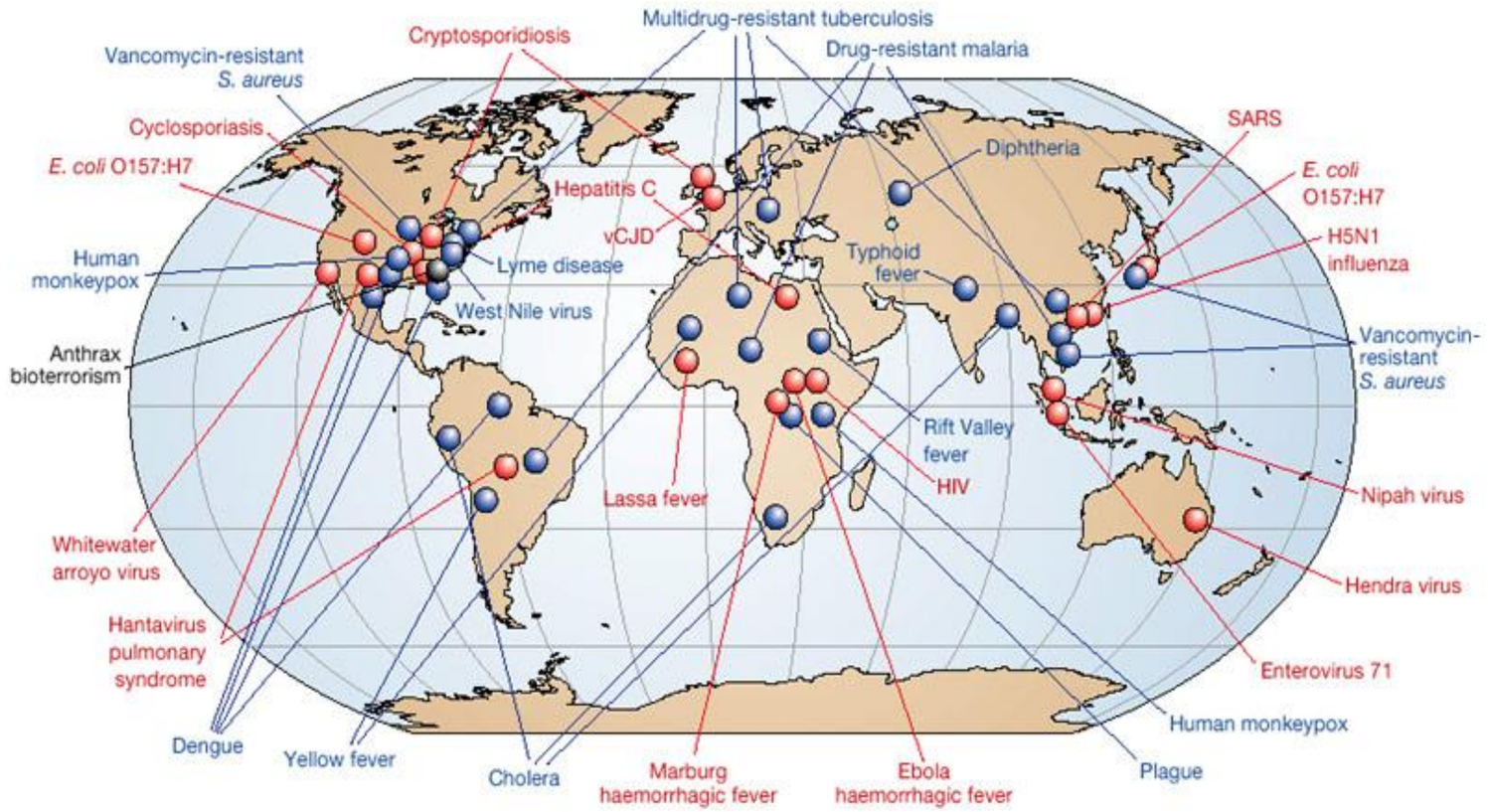
68% Only 68% of children in US are fully vaccinated by 2 yrs of age

29% Only 29% of population in developing countries vaccinated against Covid

Vaccine inequality & low public acceptance inhibit vaccine uptake and limit coverage

www.ourworldindata.org
WHO Immunization coverage 2022

Global pressure driving emerging infectious diseases (EID's)



- Global travel
- Migration
- Armed conflicts
- Increasing population & urbanisation
- Climate change

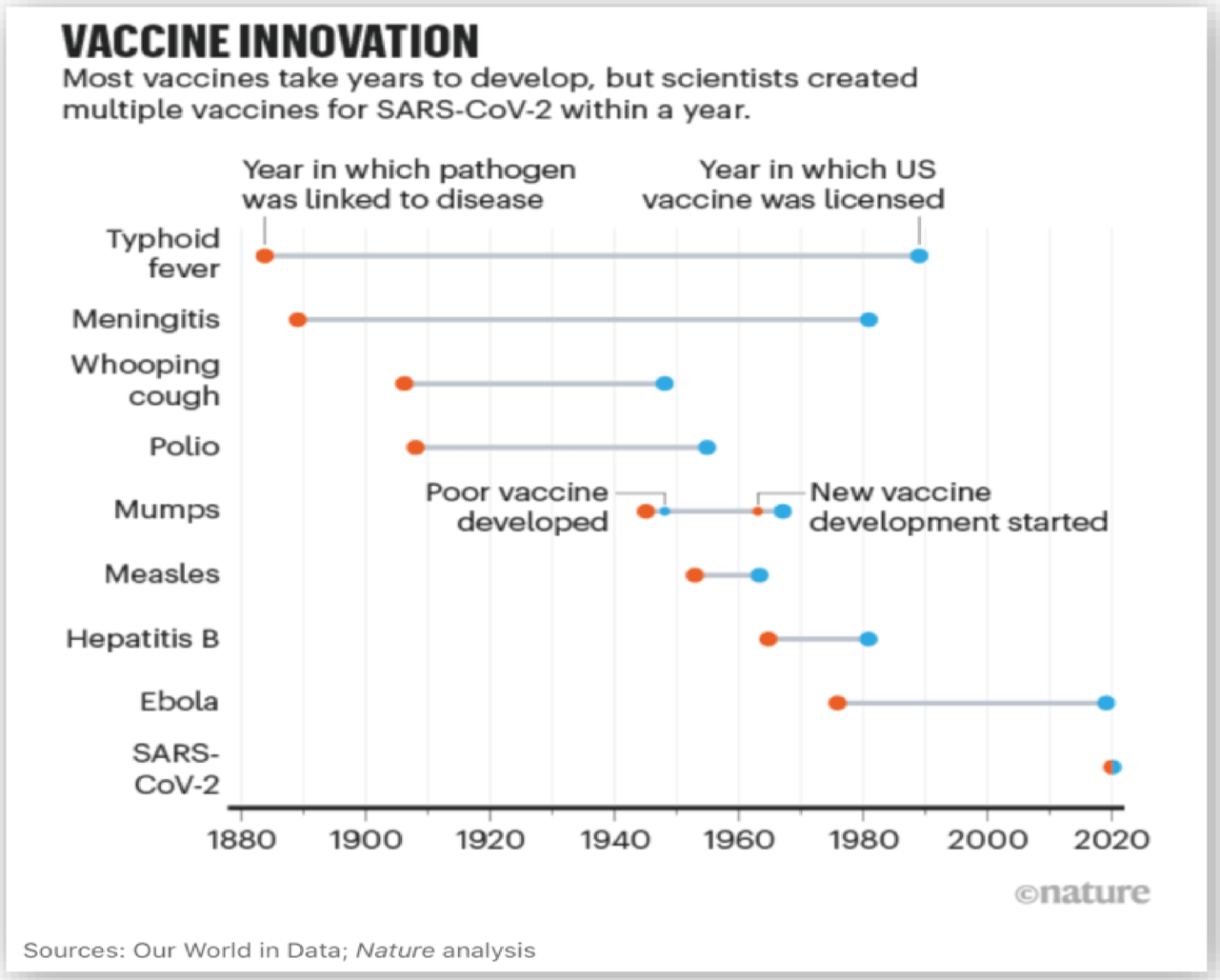
- Chikungunya Dec 2013 - Mar 2015 (Americas)
- >1.3 million cases in 44 countries

- Ebola 2014 (W.Africa)
- 20,206 cases, 7905 deaths

- MERS-CoV 2012 - 2017 (Global)
- 2027 cases in 26 countries

Lessons from COVID pandemic

Vaccine development can be accelerated



Making a Difference by:

Shortening time to clinic and licensure
Reducing vaccine manufacturing costs

using our HIP-vax® manufacturing platform

BATAVIA biosciences

Major global programs & initiatives

- Partner with BMGF to establish global biological repository of global health vaccines
  - Cell substrates: Vero, MRC-5
  - Vaccine seeds: Measles, Rubella, Polio, Rotavirus, Rabies
- Partner with BMGF and Institut Pasteur Dakar to establish vaccine manufacturing (MR) on continent of Africa
- Partner with IAVI, CEPI, BARDA, DTRA to develop VSV vaccines against Lassa, Marburg, Ebola and COVID
- Partner with PATH & BMGF to develop novel vaccines under polio eradication initiative
- Partner with University of Tokyo and CEPI to develop Nipah vaccine
- Partner with LUMC and EU to develop gene therapy treatment for severe combined immunodeficiency syndrome (RAG-1 SCID)

Recent company achievements

- Development & licensing of low-cost manufacturing process for trivalent Inactivated Polio Vaccine (IPV) at $0.40 per dose (BMGF)
- Development & licensing of low-cost, highly concentrated Measles-Rubella (MR) vaccine at $0.15 per dose, capable of supporting novel patch delivery (BMGF), GMP manufacture of MR for clinical Phase I
- Development and manufacture of VSV-Lassa vaccine for Phase I/II clinical trials (CEPI)
- Manufacture of novel, emergency use Oral Polio Vaccine materials (OPV) & tech transfer to developing country manufacturers (PATH)
- Discovery of role of mutations in polio vaccine efficacy and methods of control during manufacturing (BMGF)
- Manufacture of novel Lentivirus products for testing in Phase I clinical trials (LUMC)

HIP-Vax® Highly Intensified Vaccine Manufacturing

BATAVIA biosciences

Accelerate biotechnology

From Bench To Commercial Supply

The road towards clinical & commercial manufacturing

From:

Materials & Bench processes

To:

Clinical product ready for patient trials

To:

Commercial product ready for global use

Preparedness is the key

1

Platform manufacturing process ready to go

- Baseline manufacturing process at clinical & commercial scale
- Widely applicable to viral & vector-based vaccine (eg: live attenuated, inactivated)
- Process quickly used for clinical production with no development
- Process quickly optimized for commercial production

2

Assays for testing & release ready for use

- Optimize product storage stability
- Deliver robust assays for product characterization
- Deliver all required release tests

3

Manufacturing & release documentation templates prepared

- Manufacturing documentation for regulatory authorities in support of clinical filing (BoT, BoM, MPR's), Assay protocols developed and qualified

4

Manufacturing materials pre-ordered & maintained on stock

- Manufacturing materials available on stock and ready to go

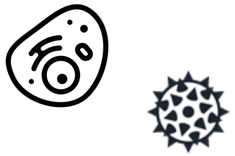
5

Produce & release clinical product

- Produce product in GMP clean room facility
- Release product for use in patients

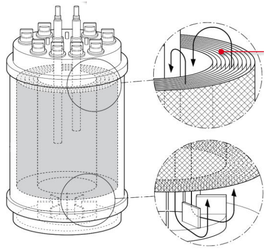
HIP-Vax®

Highly intensified manufacturing technology



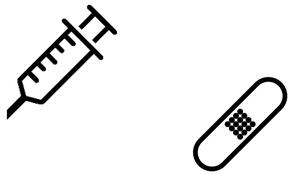
Biological materials

- GMP Cell substrates (Vero, MRC-5, HEK293)
- GMP vaccine seeds (Measles EZ, Rubella Wistar, WHO Sabin Polio, Rotavirus, Rabies, Mumps, Yellow Fever, Varicella)



Highly intensified manufacturing

- Based on innovative, fixed-bed manufacturing equipment
- Achieves ~20-fold increased process intensification compared to current technologies
- Output at 50L scale equivalent to 1000L



Platform approach

- Generic platform processes developed for multiple vaccine modalities (eg: VSV, MV, Adeno)
- Reduces time to clinical POC to <6 months and to commercial manufacturing in <10 months

Low COGs

- Production in small footprint, low-cost facility reduces CAPEX and hurdle to produce
- High yields, short production times & low FTE requirement reduces OPEX
- COGs below 1 Euro per dose

High output

- High vaccine output per year (hundreds of millions of doses)
- Flexibility to deliver multiple vaccines from single facility & respond quickly to outbreak threats

Based on fixed-bed bioreactors

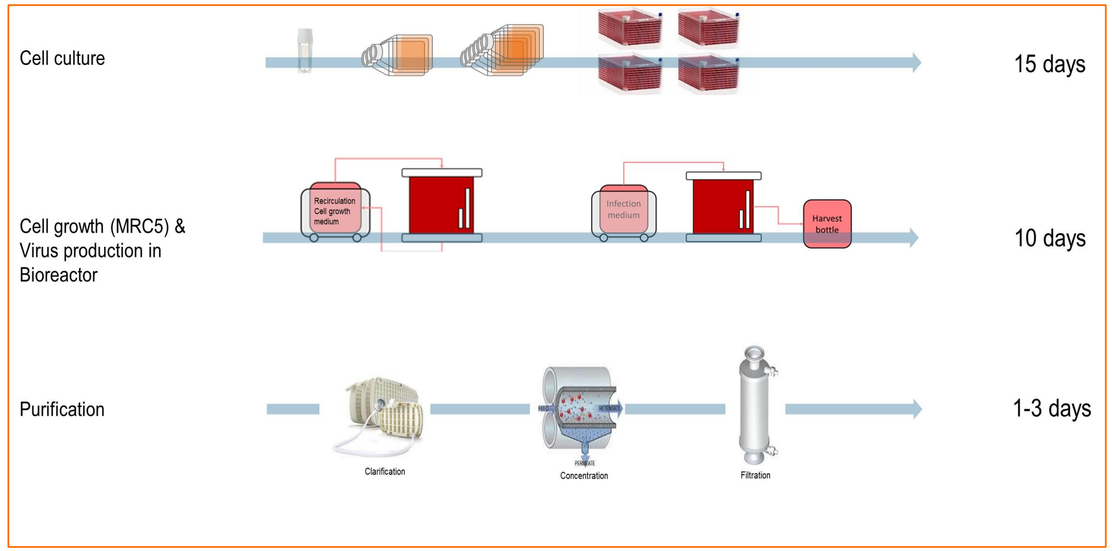
Reducing footprint of traditional technologies

scale-X™	#Roller Bottles (850cm²)	#CellFactories 40 (25.280cm²)	Stirred tank Bioreactor (Cytodex, 3 g/L)
30m²	~360	~12	~50L
600m²	~7,000	~240	~1000L

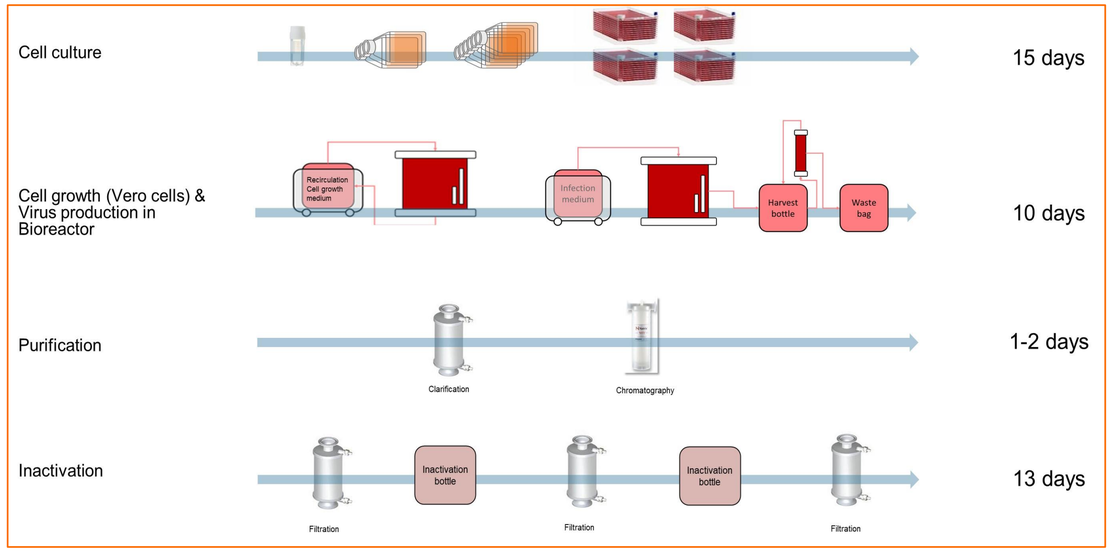
HIP-Vax®

Processes for viral vaccine classes are highly similar

Live virus manufacturing process
(eg: Measles, Rubella, VSV-vector, Measles-vector)



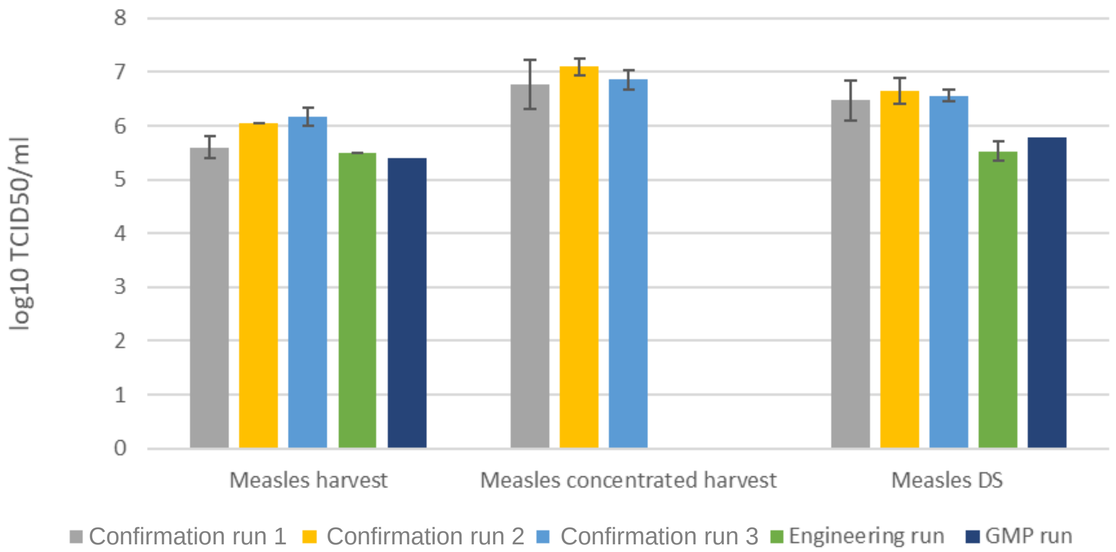
Inactivated viral vaccine process
(eg: Polio)

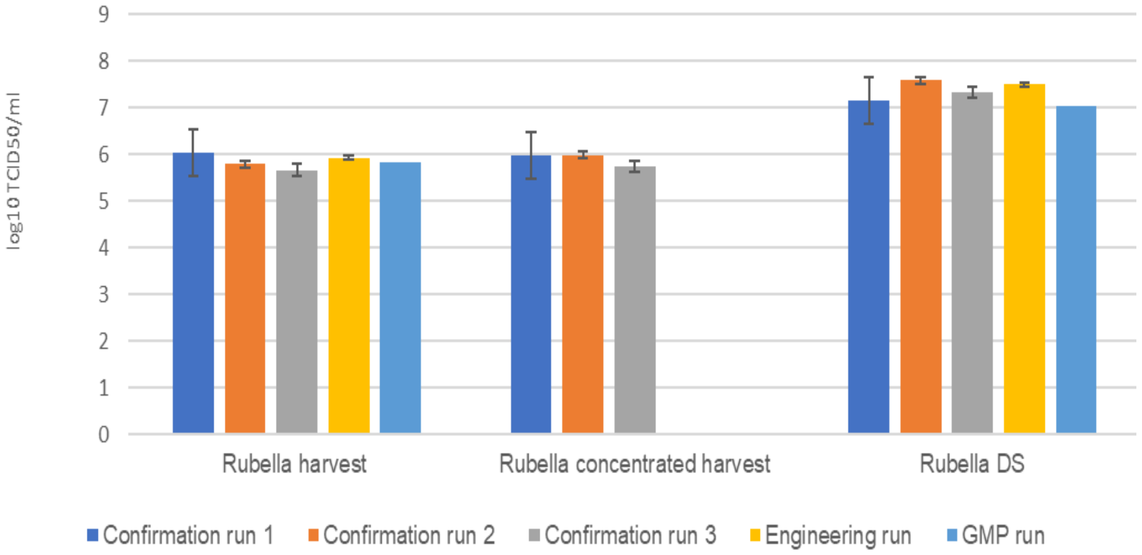


HIP-vax® platform suitable for infection, transfection and induction-based manufacturing processes.

Pilot (30m^2) scale process

Delivers 1.6M & 2.3M doses of M&R per batch

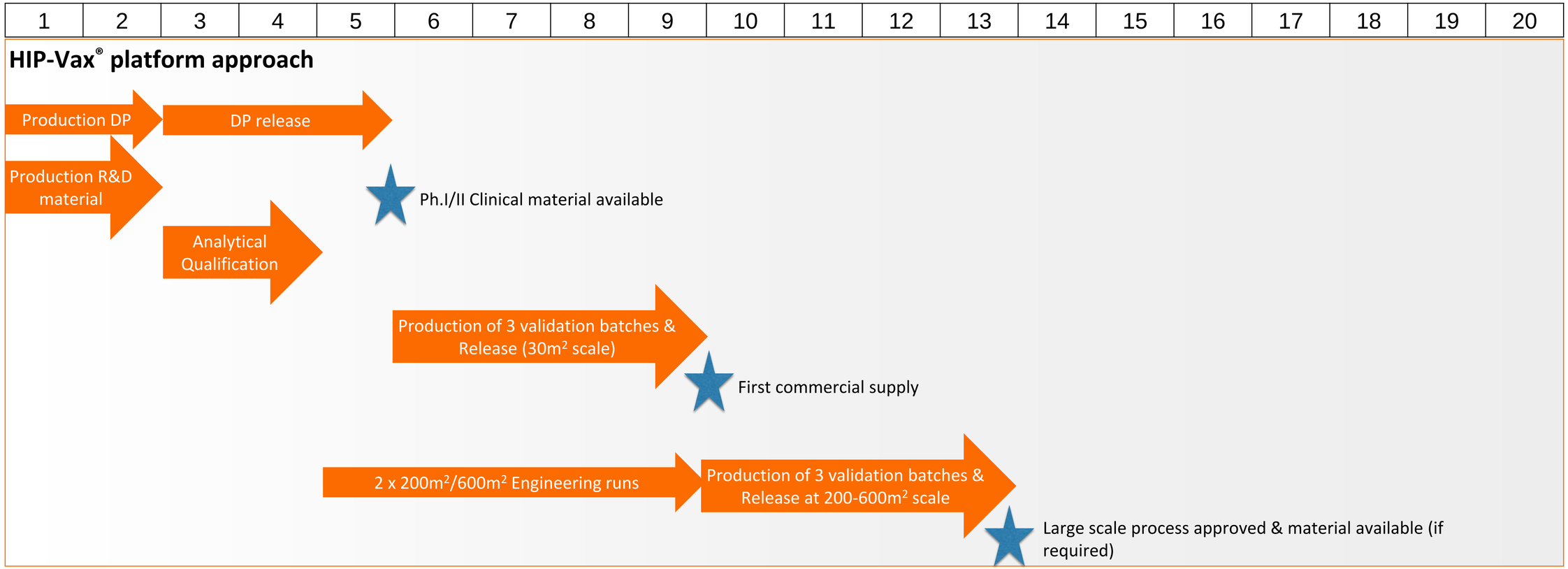




- COGs M&R at pilot (30m^2) scale: ±$ 0.32 per dose
- Highly concentrated bulks suitable for new applications (eg: MAPs)

HIP-Vax platform approach

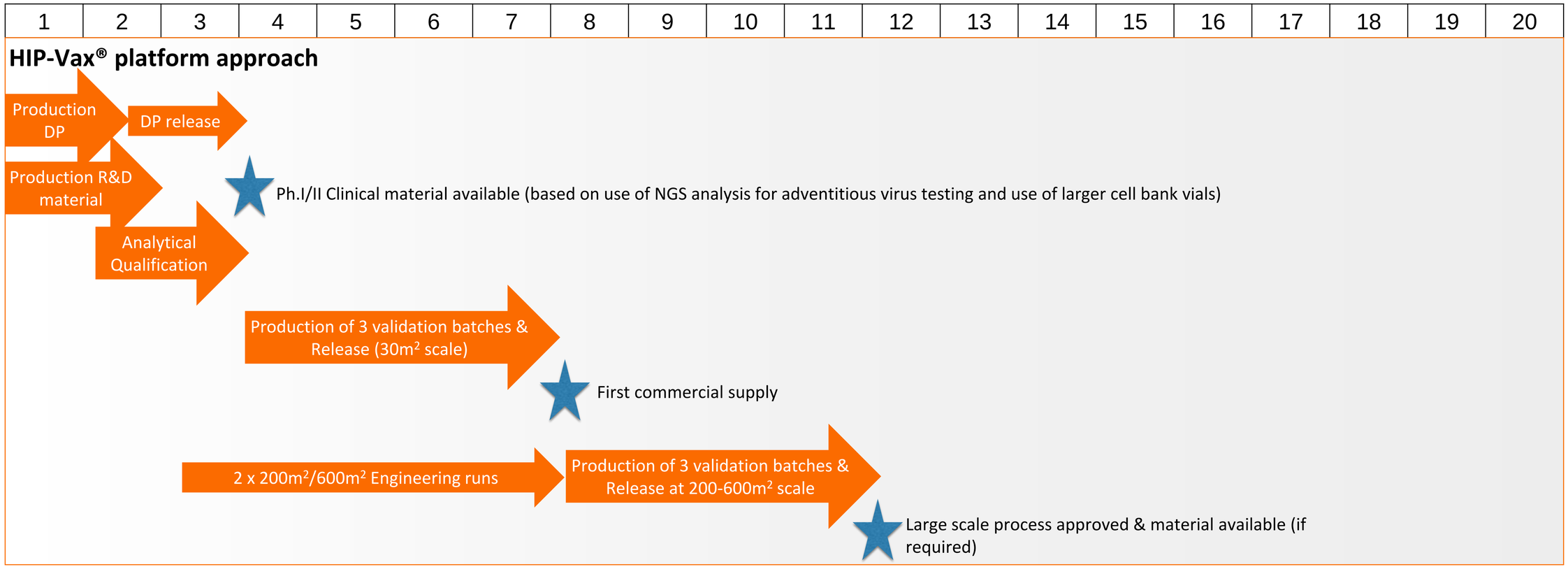
Timelines today



From concept to clinical material in 5 months and first commercial supply in 9 months

HIP-Vax platform approach

Possibilities for further acceleration



From concept to Phase I/II in 3 months and first commercial supply in 7 months

New clinical & commercial manufacturing facility in 2024

Facility located in Leiden, NL (12,000m^2, 5 Floors)

- Design, engineering & permitting completed, constructors engaged and procurement ongoing
- Construction to start early Q2 2023
- Expected facility qualification completed H2 2024

Manufacture of Viral Vaccines and Virotherapy Products

- 6 Drug substance manufacturing suites (2 clinical, 4 commercial)
- Clinical and commercial drug product aseptic filling & packaging, warehouse, QC, goods in/out
- Up to 20 clinical batches, 88 commercial batches (150-200M doses) per year
- Based on scale-X / HIP-Vax at 600M^2 scale, with capability for standard 1000L scale STR manufacturing

Thank you for your time

Feedback

We value your input and would like to hear your thoughts on the presentation,

Next steps

Let's take a moment to discuss and map out the next steps towards our shared goal.

Alfred Luitjens
+31 6 29 72 69 22
a.luitjens@bataviabiosciences.com