

LVM Landscaping Takeaways

June 2022

Executive Summary

Vaccine manufacturing progress is being made across the African continent; with public announcements made across 13 countries, mostly linked to C-19 vaccine production

Not all capacity announced expected to materialize

Existing capacity at ~60M doses p.a., with projects under way to expand to up to ~850M doses p.a. and longer-term plans for 3.2-8.2B doses

- The existing capacity on the continent is typically used to fulfill domestic demand, with most manufacturers specializing in F&F and packaging across various platforms
- Capacity expansion is focused on C-19 vaccines, though longer-term ambitions include non-Covid vaccines
- Capacity announcements focus on building ample F&F capacity (~6.4B doses), which may even exceed demand for African fill & finished vaccines should all announcements materialize
- ~1.8B doses DS capacity announced, mainly for mRNA and Viral Vector platforms; while no DS capacity announced for traditional platforms required to meet PAVM forecasted demand

Beyond C-19, the first countries and manufacturers have announced which other vaccines they are targeting, but plans are still vague and not fully transparent

Vaccine manufacturing progress is being made across the African continent—public announcements were made across 13 countries, mostly linked to C-19 production



North Africa Algeria

- Saidal & Sinovac/ 15M/2021/ Covid-19 F&F
- Saidal/Sputnik/15M/2021/F&F

Egypt (Afrigen spoke)

- Vacsera/Sinovac/200M**/'21/F&F
- Pharco/Sinovac /20-60M/'21
- Pharco/Sputnik /25M/'21
- Minapharm/Sputnik/40m

Morocco

- Sothema/Sinopharm/60m/F&F
- · Galenica/Sputnik/ (not enough data)
- Recipharm/300M/'23/F&F
- Sensyo Pharmatech/100m/'22/F&F

Tunisia (Afrigen spoke)

• Plan to establish Vx plant with Japanese partners

West Africa

Ghana

- Plans to produce C-19 Vx & Vx for other diseases **Nigeria** (Afrigen spoke)
- Afreximbank funding Vx plant with Gateway Pharma/
- Biovaccines Nigeria Ltd/ Mrna & others/710M/F&F
- Innovative Biotech/VLP/150m/F&F
- NIBI/Various/500m/F&F

Senegal (Afrigen spoke)

Institute Pasteur de Dakar/ mRNA (50M) & VV (300M)/ '22

Southern Africa

Botswana

 NantBotswana & Texas CH & Baylor College/ Corbevax/ (not enough data)/

South Africa (Afrigen spoke)

- Aspen Pharmacare & J&J/Ad26.COV 2.S & Aspenovax/500M/'21/F&F
- mRNA Tech-Transfer Hub/ Afrigen mRNA /250M/'22/E2E
- Biovac & Pfizer-BioNTech/Comirnaty/100M/'22/F&F
- Nant-SA/hAd5-COVID-19 & Corbevax /1B/'22/scale up to E2E

East Africa

Ethiopia

• Plans to produce Vx for other diseases

Kenya (Afrigen spoke)

• Establishing C-19 Vx plant/2022 pledged start

Rwanda

• BioNTech/mRNA Vx/50M, then moving to TB and Malaria

Tanzania

• Establishing Vx plant for C-19 and other diseases

Uganda

• Del Pharma establishing a Biologicals / mRNA Vx facility

Africa

• Moderna planning 500M mRNA DS to F&F Facility

Legend:



Capacity planned

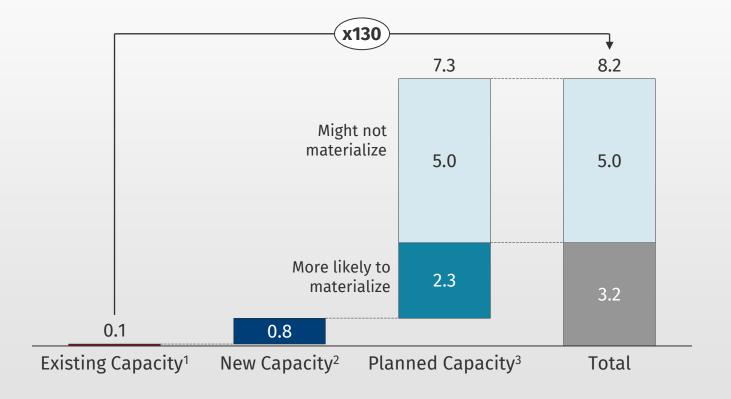
ı

In discussions

Details: Local Manufacturer/ Vaccine name or type/ Estimated Annual Production/ Publicly Announced Production start/Type of Production

Capacity announcements made in 2021/22 would increase existing Vx manufacturing capacity from ~60M doses today to >8B doses—not all capacity expected to materialize

Doses (B), Existing & Target Capacity

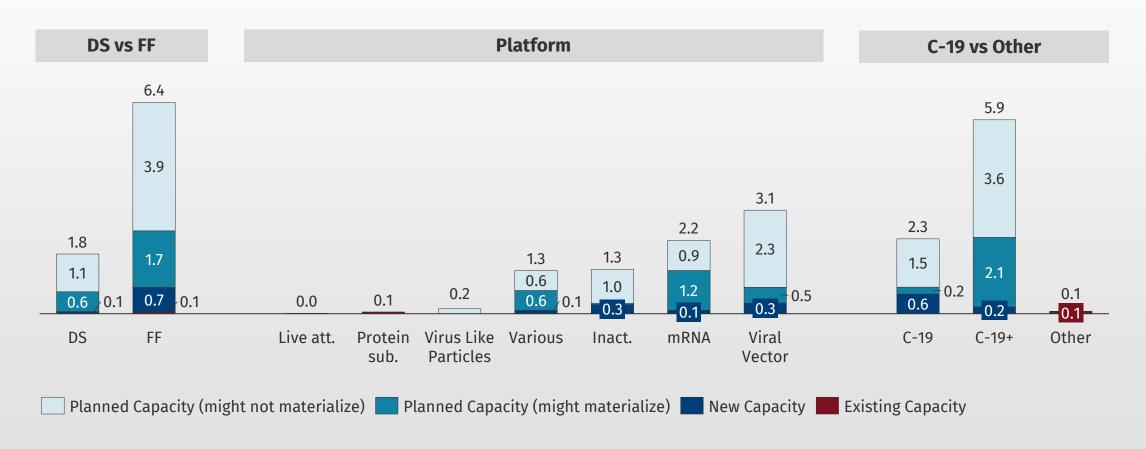


- Since the start of the COVID pandemic, there has been a surge in vaccine capacity announcements, with nearly 8 B doses of new and additional capacity announced
- The materialization of this capacity could significantly increase share of local manufacturing beyond demand expectations
- 5B doses of mostly C-19 capacity may not materialize due to the failure of production agreements, the closure of C-19 production lines due to low vaccine uptake, and the uncertainty surrounding Sputnik V vaccine supply as a result of Russian sanctions.

^{1.} Existing local manufacturing for both DS and F&F 2. Ongoing (i.e., production has started) and imminent / funded capacity; 3. Planned/expected volumes - may include non-covid capacity not publicly announced; CHAI's "LVM-Landscape-Baseline-June-01-2022" database of LVM commitments; CHAI calculations;

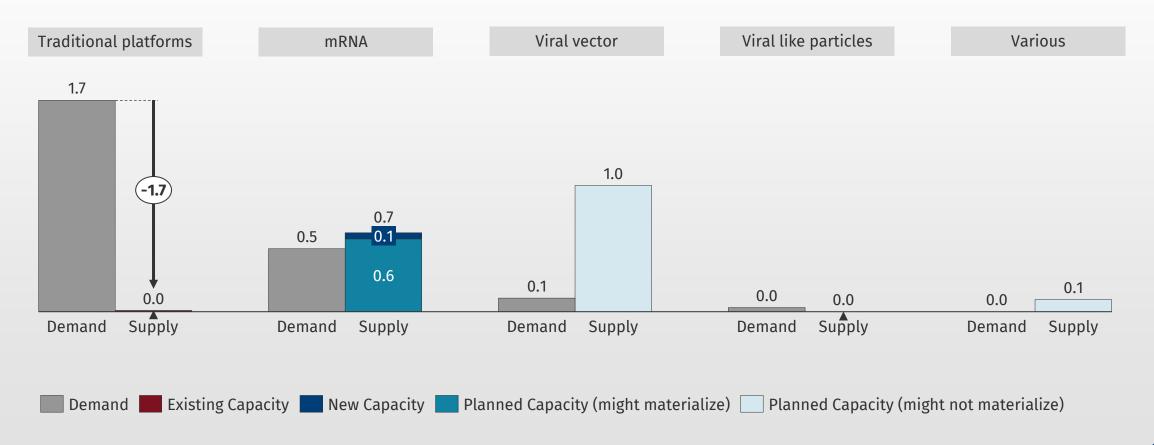
Planned capacity is predominantly for the F&F of mRNA and Viral Vector vaccines; while much capacity has been foreseen for C-19, suppliers are considering other vaccines

Doses (B), Existing & Target Capacity



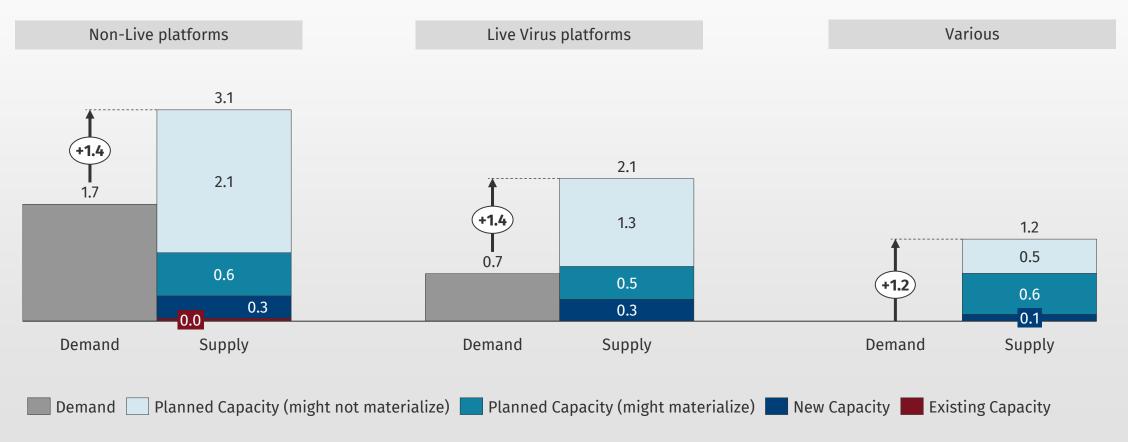
DS capacity announced mainly for mRNA and Viral Vector platforms, while no DS capacity announced for traditional platforms required to meet PAVM forecasted demand

Doses (B), Demand vs Drug Substance Capacity

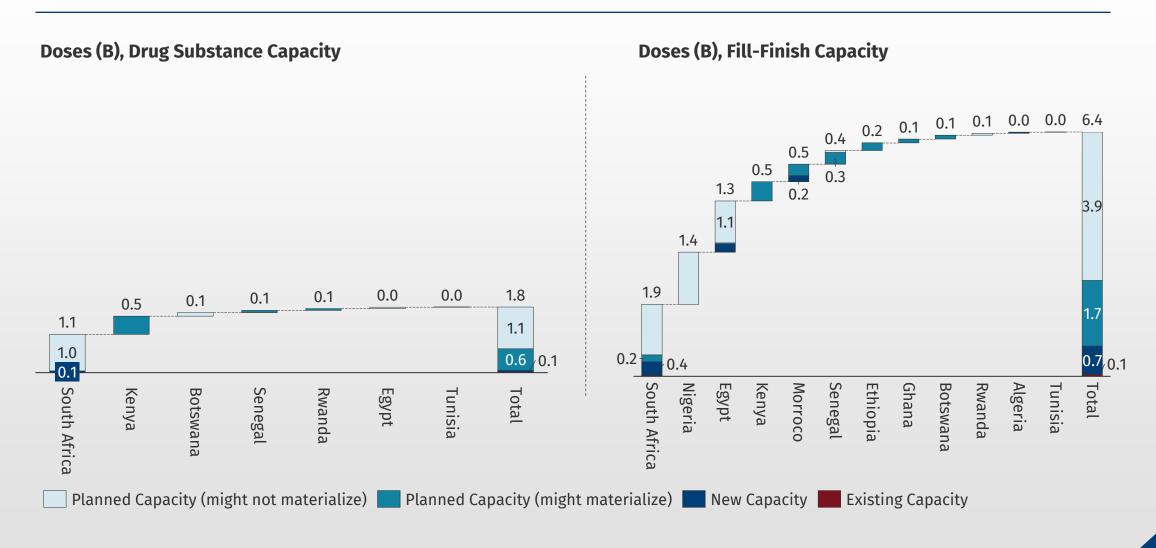


Ample F&F capacity should all announcements materialize; potential shortfalls for non-live platforms

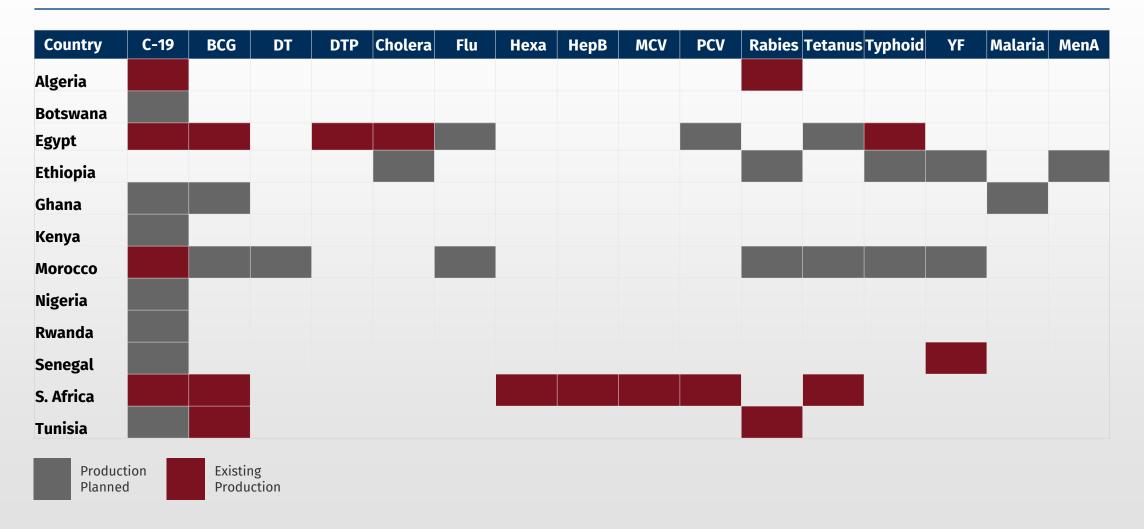
Doses (B), Demand vs Fill-Finish Capacity



Most countries with plans for F&F, of which seven also target DS production: different levels of certainty with regards to materialization observed



Beyond C-19, countries/manufacturers intend to expand to other vaccines—but plans still vague



Deep-dive Africa

The following slides provide an overview of donor commitments and tech-transfers to select African countries which are experiencing high level of LVM activities....

South Africa: Despite concerns with uptake, South Africa has ongoing plans to produce, sell & distribute vaccines following significant investments in local manufacturing last year & new agreements with global partners.

- Following significant investment (\$912M) to support local fill & finish of J&J C-19 vaccines, Aspen has reported partial production of 120 million doses of the J&J COVID-19 vaccine as of Dec 2021.
- Aspen has secured a deal with J&J that will make Aspen the first African company to have the rights to distribute and price the Covid-19 vaccine, which it would market under its own brand name of Aspenovax As of May 2022, Aspenovax had not received any orders, which is concerning.
- WHO has announced the first six African countries (the spokes) that will receive tech-transfers from the SA mRNA Hub. This comes off the back of the news of Afrigen successfully replicating Moderna's COVID-19 vaccine.
- Biovac to start final stages of production of Pfizer's C-19 shot in Q3/Q4 2022 through it's C-19 Vx partnerships across the vaccine value chain, most notably with WHO's mRNA hub and Pfizer BioNTech; Biovac also has ongoing technology transfers predating C-19 with Pfizer (PCV13) and Sanofi (Hexa)
- ImmunityBio is testing a novel C-19 candidate in South Africa

Lead Partner/ Donor	Beneficiary	Type of Commitment ¹	Primary Focus Area	Addtl. Details	Maturity
International Finance Corporation (IFC)	Aspen	Debt financing (\$712 million)	Manufacturing	-	Medium - Funding committed
USA Government (in support of J&J tech transfer)	Aspen	Equity financing (\$200 million)	Manufacturing	Fill-finish	Medium - Funding committed
J&J	Aspen	Tech-Transfer	Manufacturing	Fill-finish & sales	High – Production has started
J&J	Aspen	Licencing	Sales & Distribution	-	High- Agreement signed
Consortium of 9 DFIs	Biovac	Ecosystem Building (\$150 million)	Manufacturing	-	Medium – Partnership announced
FCDO	BioVac	Grant	Strategy & Planning	Feasibility study	Medium - Funding committed
Pfizer BioNTech	Biovac	Tech-Transfer	Manufacturing	Fill-finish	Medium – Agreement in place
Afrigen	Biovac	Tech-Transfer	Manufacturing	-	High – confirmed spoke
WHO	Afrigen & Biovac (mRNA hub)	Ecosystem Building (\$100 million)	Overarching	-	High – Consortium set up, roadmap in place & +50% of funding raised.
NantWorks/Dr Patrick Soon- Shiong.	NantSA	Investment/Equity	Manufacturing	-	Medium – NantSA has secured land & warehouse space
Kentucky Bioprocessing (KBP)	CSIR	Ecosystem Building	R&D	-	Low – discussions underway
Dyadic	Rubic Consortium	Tech-Transfer	R&D and Manufacturing	-	Medium – phase 1 CT underway

^{1. &}quot;Tech-transfers" refers to supplier-to-supplier transfer of technology; "Ecosystem Building" refers to pharmaceutical technology capacity development

Senegal: Vaccine production capacity at IPD will be scaled up more quickly through innovative vaccine filling technology, providing rapid delivery of vaccines to Africa.

- MADIBA (Manufacturing in Africa for Disease Immunization and Building Autonomy) project at IPD expected to have a capacity of 25M Covid-19 vaccine doses per month & 300M doses per year.
- Project timelines: DS Design and Construction 2022, Licensing Amendments Submitted 2022/23; DS Qualification 2023, DS Production 2023/24
- Univercells is planning to transfer DS production for C-19 Vx (likely viral vector) to Senegal in mid- 2022
- KeyPlants, a Swedish provider of innovative life science facilities and PODs, has shipped a vaccine manufacturing filling facility to Senegal.
- The base plan is to use the MedInstill/Intact filling system and multi-dose injector in a mix of pouches and vials. Vial filling process already EMA approved.
- 'Team Europe' supporting Senegal towards the strengthening of the country's NRA. Senegal is addressing gaps required to achieve as NRA ML3.
- The European Investment Bank and Germany's KfW development bank supporting IPD scale up production of rapid diagnostic testing kits for use by front-line health workers across Africa.
- IPD has been confirmed as a SA mRNA Hub's spoke

Lead Partner/ Donor	Beneficiary	Type of Commitment	Primary Focus Area	Addtl. Details	Maturity
"Team Europe" *	Institut Pasteur in Dakar	Grants (\$7,9 million)	Strategy & Planning	Feasibility study	High – agreement signed
Germany's Federal Ministry for Economic Cooperation and Development (BMZ)	Institut Pasteur in Dakar	Grant (\$23,5 million)	General	-	High – agreement signed
Agence Française de Développement (AFD)	Institut Pasteur in Dakar	Grant (\$2,1 million)	Strategy & Planning	Feasibility study	High – agreement signed
European Commission	Institut Pasteur in Dakar	Grant (amount tbd)	Manufacturing	-	Low – under discussion
US DFC	Institut Pasteur in Dakar	Grant (\$3,3 million)	Manufacturing	-	High – agreement signed
IFC	Institut Pasteur in Dakar	Grant (\$3,3 million)	Manufacturing	-	High – agreement signed
FCDO	Institut Pasteur in Dakar	Grant	Strategy & Planning	Feasibility study	Medium – funding committed
Bill and Melinda Gates Foundation	Institut Pasteur in Dakar	Grants (\$4,9 million)	Strategy & Planning	-	High – agreement signed
Afrigen	Institut Pasteur in Dakar	Tech-Transfer	Manufacturing	-	High – confirmed spoke
Univercells	Institut Pasteur in Dakar	Tech-Transfer	Manufacturing	Full value-chain	Medium - letter of intent signed
Univercells	Institute for Health Research("IRESSEF")	Tech-Transfer	R&D	-	Medium - letter of intent signed
BioNTech	Institut Pasteur in Dakar	Tech-Transfer	Manufacturing	-	Medium - agreement signed
CEPI	Institut Pasteur in Dakar	Unspecified	Strategy & Planning	-	Medium - MoU signed

^{1. *}Team Europe includes: (EU, EU Member States — including their implementing agencies and public development banks —, EIB and EBRD)

^{2. &}quot;Tech-transfers" refers to supplier-to-supplier transfer of technology; "Ecosystem Building" refers to pharmaceutical technology capacity development

Rest of Africa: Commitments are scattered & mainly driven by local government initiatives to build Vx manufacturing capacity with support from Chinese & Russian manufacturers; but less concerted global donor action.

Country/Region	Lead Partner/ Donor	Beneficiary	Type of Commitment	Primary Focus area	Maturity
Algeria	Gamaleya Research Institute	Saidal	Tech-Transfer	Manufacturing	High - Tech-transfer already in motion
Algeria	Sinovac	Saidal	Tech-Transfer	Manufacturing	High - Tech-transfer already in motion
Botswana	Texas Children's Hospital and BC	NantBotswana	Tech-Transfer	Manufacturing	High - Tech-transfer already in motion
Botswana	Dr Patrick Soon-Shiong/ Nantworks	Botswana Government	Investment/Equity	Manufacturing	Medium - MoU signed
Egypt	Gamaleya Research Institute	Minapharm	Tech-Transfer	Manufacturing	Medium – Tech-transfer announced
Egypt	Sinovac	VACSERA	Tech-Transfer	Manufacturing	High - Tech-transfer already in motion
Egypt	Afrigen	Biogeneric	Tech-Transfer	Manufacturing	High – confirmed spoke
Egypt	EVA Pharma	-	Investment/Equity	Manufacturing	High – plant construction underway
Ghana	International Vaccine Institute	KNUST	Ecosystem Building	R&D	Medium - MoU signed
Ghana	Government of Ghana	-	Public Funding (\$25 million)	Manufacturing	High - financing committed
Kenya	Afrigen	AKDN	Tech-Transfer	Manufacturing	High – confirmed spoke
Kenya	Government of Kenya	-	Public Funding	Manufacturing	Low - in initial discussion stages
Morocco	Government of Morocco	Recipharm	Public Funding (\$500 million)	Manufacturing	High – financing committed
Morocco	Sinopharm	Sothema	Tech-Transfer	Manufacturing	Medium – deal signed
Nigeria	Afrigen	Biovaccines Nigeria Ltd	Tech-Transfer	Manufacturing	High – confirmed spoke
Nigeria	World Bank	Biovaccines	Financing (\$30 million)	Manufacturing	Low - initial financing discussions underway
Nigeria	Afreximbank	Gateway Pharma	Ecosystem Building (\$200M pledge)	Overarching	Medium – pledge announced
Rwanda	European Union	Rwanda FDA	Loan (\$3,6 million)	Strategy & Planning	Medium - agreement has been signed
Rwanda	International Finance Corporation	Rwanda Develop. Board	Unspecified	Manufacturing	Medium - agreement has been signed
Rwanda & Senegal	BioNTech	Rwandan Government	Tech-transfer	Manufacturing	Medium - agreement signed
Tanzania	Government of Tanzania	-	Public Funding	Manufacturing	Low – under consideration
Tunisia	Afrigen	Pasteur Institute of Tunis	Tech-Transfer	Manufacturing	High – confirmed spoke
Africa (unspecified)	European Union	Africa Region	Ecosystem Building (\$1 billion)	Overarching	High – some initiatives have been rolled out
Africa (unspecified)	Mastercard Foundation	Africa Region	Ecosystem Building (\$1,3 billion – not all for LVM)	Overarching	Medium – pledge announced
Africa (unspecified)	Afreximbank & Africa Finance Corp.	Africa Region	-	Overarching	Medium - agreement has been signed
Africa (unspecified)	Moderna	Africa Region	Equity financing	Manufacturing	Low - in initial discussion stages



www.clintonhealthaccess.org