COVID Vaccine & Therapeutics Update

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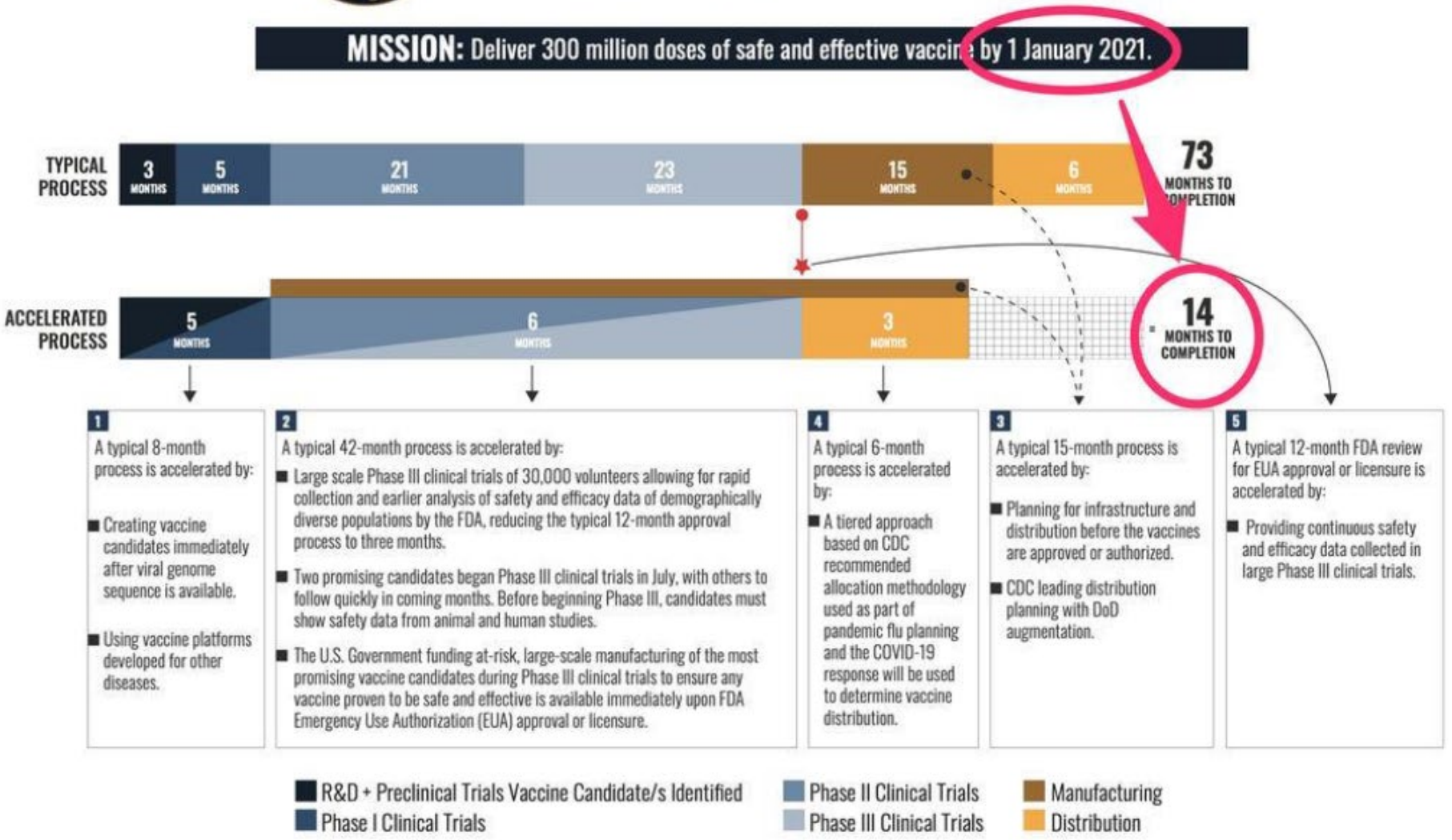
EHPC Quarterly Meeting – Nov. 12, 2020

OPERATION WARP SPEED
ACCELERATED VACCINE PROCESS



https://www.businessinsider.com/coronavirus-vaccine-timeline-trump-operation-warp-speed-timeline-2020-8 - accessed 8/18/2020

FDA Published Guidance for Industry for COVID Vaccines

- June 2020: Development & Licensure of Vaccines to Prevent COVID-19
  - Key Principles
    - Phase 3 trials should be Randomized, Placebo-controlled Efficacy Trials
    - ~30,000 volunteers
    - Study population: Diverse, ≥ 18 yo, with subsets in high-risk groups
    - Primary Endpoint: Prevention of symptomatic COVID-19 disease
      - Primary efficacy endpoint at least 50%
    - Common Data Safety Monitoring Board (DSMB) across all trials (NIAID)
- October 2020: Emergency Use Authorization for Vaccines to Prevent COVID-19
  - Lays out what FDA will be looking for in EUA application
  - Median follow up duration of at least 2 months after full vaccination regimen to provide adequate information to assess a vaccine's benefit-risk profile

Front Runner Vaccine Candidates

Company	Candidate	Platform	Current Phase	OWS Funding	Dose commitment
AstraZeneca/Oxford Univ.	AZD1222	Viral vector	3	$1.2B	300M
Moderna	mRNA-1723	mRNA	3	$1.5B	100M
Johnson & Johnson (Janssen)	Ad26 SARS-CoV-2	Viral vector	3	$1.5B	100M
Novavax	NVX-CoV2373	Protein subunit	2	$1.6B	100M
Pfizer/BioNTech	BNT162	mRNA	2/3	$1.95B	100M
GlaxoSmithKline/Sanofi	-----	Protein subunit	1/2	$2.1B	100M

Interested in participating in a COVID Vaccine Trial?

COVID-19 Prevention Network – Volunteer Registry

COVID-19 Vaccine Planning Assumptions

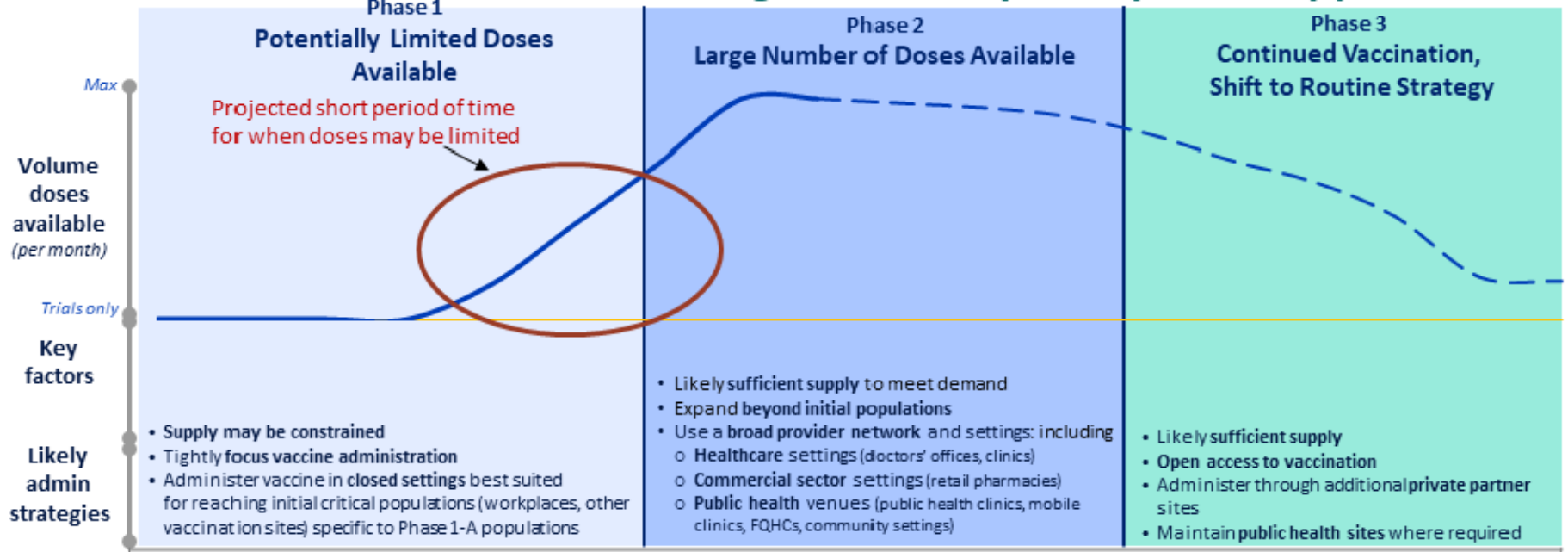
- Limited COVID-19 doses will be available in late 2020, likely via EUA
  - CDC has given states an operational readiness date of 11/15
  - Large scale vaccination campaign likely to occur in 2021
- Likely 2 dose vaccine series
  - ≥21 or ≥28 days apart, must be the same product
- Some vaccine candidates require ultra-low cold storage (-70°C ± 10°C)
  - It is NOT recommended to purchase ULC storage
- Some vaccine candidates will likely require reconstitution with diluent or adjuvant at the point of administration
- Ancillary supplies will be “kitted” and shipped separately
  - Timed to arrive with or before vaccine
  - Does NOT include sharps containers, gloves or bandages

COVID-19 Vaccine Planning Assumptions cont'd

- Providers should NOT hold back vaccine for second dose
- Vaccine A from CDC playbook expected to be first available
  - Requires ULC storage
  - 2 doses ≥ 21 days apart
  - ~1,000 dose minimum allocation size
  - Expected packaging of Pfizer vaccine presented to ACIP in August (1:36:00 mark)
  - Ships direct from manufacturer
- All other vaccine candidates expected to have ~100 dose minimum allocation
  - Ship through central distributor (McKesson)
- Overall Phased Approach (see next slide)

Projected COVID-19 Vaccine Program Phases

The COVID-19 Vaccination Program will require a phased approach



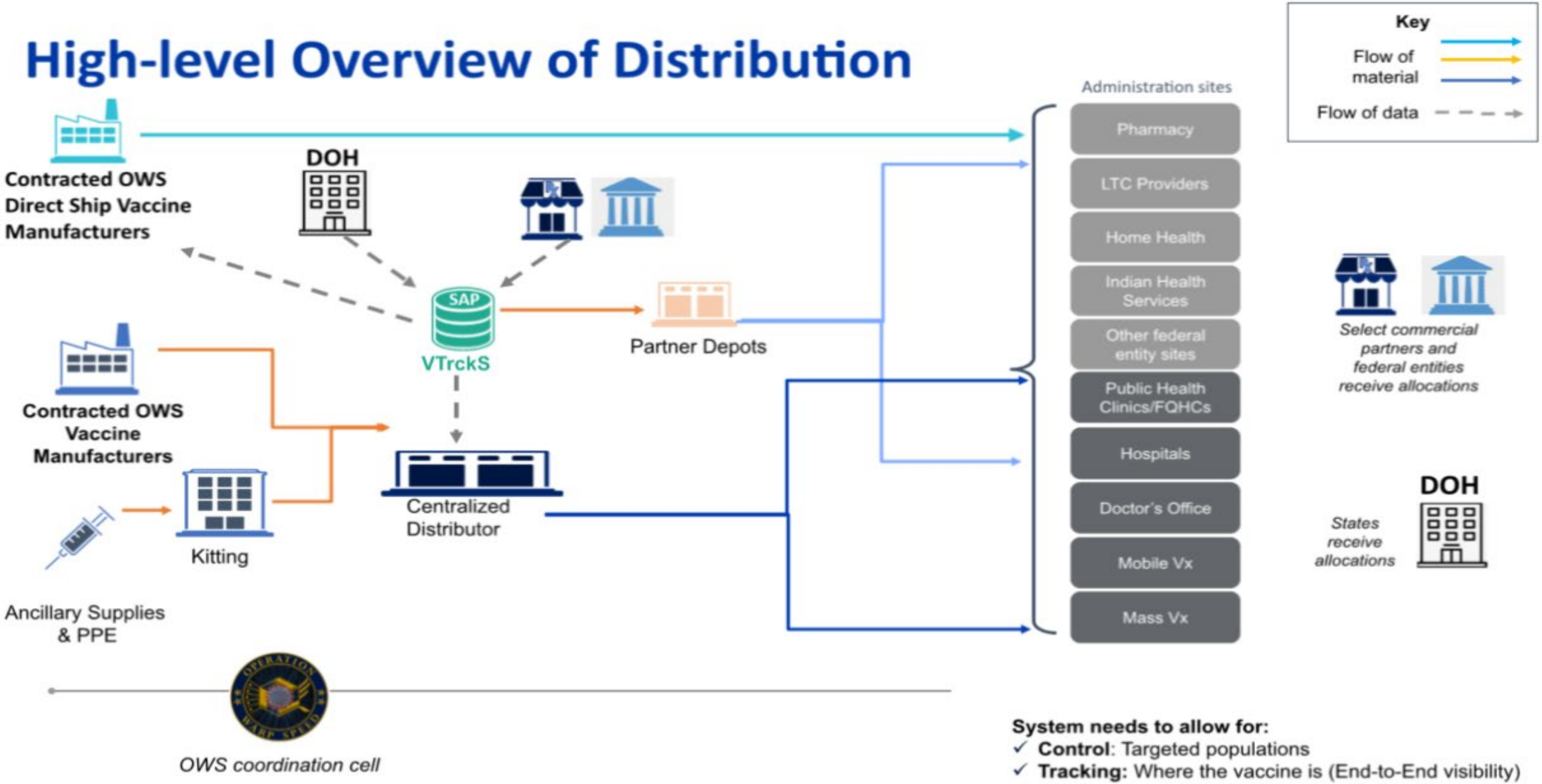
Populations of Focus*		
Phase 1	**Phase 2**	**Phase 3**
Phase 1-A: • Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.	• Remainder of Phase 1 populations • Critical populations** • General population	• Remainder of Phase 1 populations • Critical populations** • General population
Phase 1-B: • Other essential workers • People at higher risk of severe COVID-19 illness, including people 65 years of age and older		

9/4/20

**Planning should consider that there may be initial age restrictions for vaccine products.*

***See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.*

High-level Overview of Distribution



CDC, August 2020

Federal Level Vaccine Planning Initiatives

- CDC's COVID-19 Vaccine Playbook
  - Version 2 published 10/29/2020
- Federal LTC-Retail Pharmacy Partnership
  - Retail pharmacies to provide on-site, end to end vaccine management
    - SNFs and ALFs eligible – Free of charge
  - Opt-in period ended 11/6 – but still a way to get in if interested
  - State POC: William.Krepps@dhhs.nc.gov
- Federal retail pharmacy partnership program
  - Appendix I (pg. 74) of current CDC playbook
  - Direct allocations of vaccine to retail pharmacy partners to provide vaccine services to the general public
  - This would be operationalized only when vaccine supply and prioritization allow

State Level Vaccine Planning Activities:

- NC Interim COVID-19 Vaccination Plan
  - Published 10/16/2020
  - Currently under review for 2nd version
- External Advisory Committee (NC Institute of Medicine)
  - Developed NC Prioritization Framework (found in NC Vaccine plan)
- Public Outreach & Historically Marginalized Populations Workgroup
- Provider Enrollment
  - Every provider wishing to receive/administer COVID Vaccine must sign agreement to officially enroll
- COVID Vaccine Management System (CVMS)
  - Day to day administration management platform
  - Custom built, meets CDC data reporting requirements, feeds data back to NCIR

Local Vaccine Planning Suggestions:

- Form local COVID vaccine planning team
- Review Federal and State planning documents
- Assess existing LHD mass vaccination plans
- Review H1N1 lessons learned
- Think about high-risk groups in your community and ways to reach them
- Stay current with the latest information

Additional Sources of Information

Advisory Committee on Immunization Practices (ACIP)

FDA COVID-19 Website

Clinicaltrials.gov

CDC COVID-19 Website

North Carolina COVID-19 Dashboard

WHO – Draft Landscape of COVID-19 Candidate Vaccines

COVID-19 Therapeutics Update - Veklury

- Veklury® (Remdesivir)
  - FDA approved on 10/22
    - Patients age 12+, who weigh at least 40kg and require hospitalization
  - EUA remains for hospitalized pediatric patients
    - Patients weighing 3.5 to less than 40kg –OR-
    - Patients less than 12yo and weighing at least 3.5kg
  - No change in procurement process or cost
    - AmerisourceBergen is sole distributor through at least the end of 2020

COVID-19 Therapeutics Update - bamlanivimab

- Bamlanivimab
  - Manufactured by Eli Lilly
  - mAbs work by directly neutralizing the COVID-19 virus
  - Intended to prevent progression of disease
  - Product given via single IV infusion
- Emergency Use Authorization granted 11/9/2020
  - Early evidence showed potential to reduce hospitalization for infected people if given early in infection – BLAZE-1 clinical trial
  - Intended for use in outpatient setting
    - May actually worsen outcomes if given to patients who are already hospitalized

Bamlanivimab EUA Requirements

- Bamlanivimab is authorized for patients:
  - 12+ years old weighing at least 40 kg who are at high risk of progressing to severe COVID-19 and/or hospitalization
  - Must be administered as soon as possible after + COVID test AND within 10 days of symptom onset

- Bamlanivimab is NOT authorized for patients who:
  - Are hospitalized due to COVID-19 –OR-
  - Require oxygen therapy due to COVID-19 –OR-
  - Require and increase is baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy sue to underlying NON-COVID-19 related comorbidity.

Bamlanivimab EUA Requirements

- High-risk Criteria for EUA (patients must have at least 1)
  - BMI ≥ 35
  - Chronic Kidney disease
  - Diabetes
  - Immunosuppressive disease
  - Receiving Immunosuppressive treatment
  - Age ≥ 65
  - Age ≥ 55 PLUS
    - Cardiovascular disease –OR- hypertension –OR- COPD/chronic respiratory disease
  - Age 12-17 PLUS
    - BMI > 85th percentile for age & gender OR
    - Sickle cell disease OR
    - Congenital or acquired heart disease OR
    - Neurodevelopment disorders OR
    - A medical related technology dependence OR
    - Asthma, reactive airway or other chronic respiratory disease requiring daily medication for control

Bamlanivimab EUA considerations

- 700mg via IV infusion over at least 60 mins via pump or gravity
- Clinical monitoring of patients during and for at least 1 hour after infusion is complete
- Patients treated with bamlanivimab should continue to self-isolate and use recommended infection control measures
- Product requires storage at 2-8^{o}C protected from light
- May only be administered in settings in which healthcare providers have immediate access to medications to treat a sever infusion reaction and have the ability to activate the emergency medical system as necessary

Bamlanivimab EUA considerations

- Phase 1 of Bamlanivimab distribution
  - Intended for outpatient use by hospitals or hospital affiliated locations
    - Emergency Departments
    - “Hospitals without walls” – Temporary structures, virtual hospitals
    - Skilled Nursing facilities
    - Infusion centers
    - Urgent Care Centers
    - Other hospital affiliated clinics
- Phase 2 of Bamlanivimab distribution
  - Will allow for distribution to non-hospital affiliated locations capable of meeting EUA requirements
- No timeline for transition between phases
  - HHS/ASPR taking a wait and see approach

Bamlanivimab Challenges

- Supply
  - 300,000 doses total available by end of 2020
  - US Gov't has purchased and is providing free of charge
  - Us Gov't has the option to purchase additional doses
- Administration Locations
  - Dealing with COVID + patients
    - keeping workers and non-COVID-19 patients safe
  - Eventual broad range of possible administration locations
- Connecting patients to treatment
  - Narrow timeframe for administration

Questions?

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