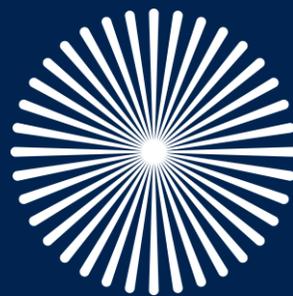
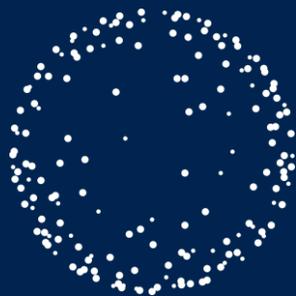
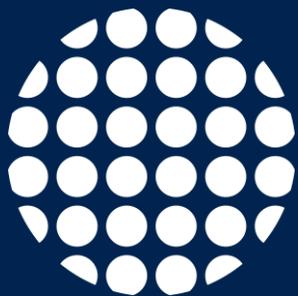


CEPI's Lassa Vaccine Development Activities: Vaccine Portfolio and Epidemiology Programme

Date: 27th January 2020

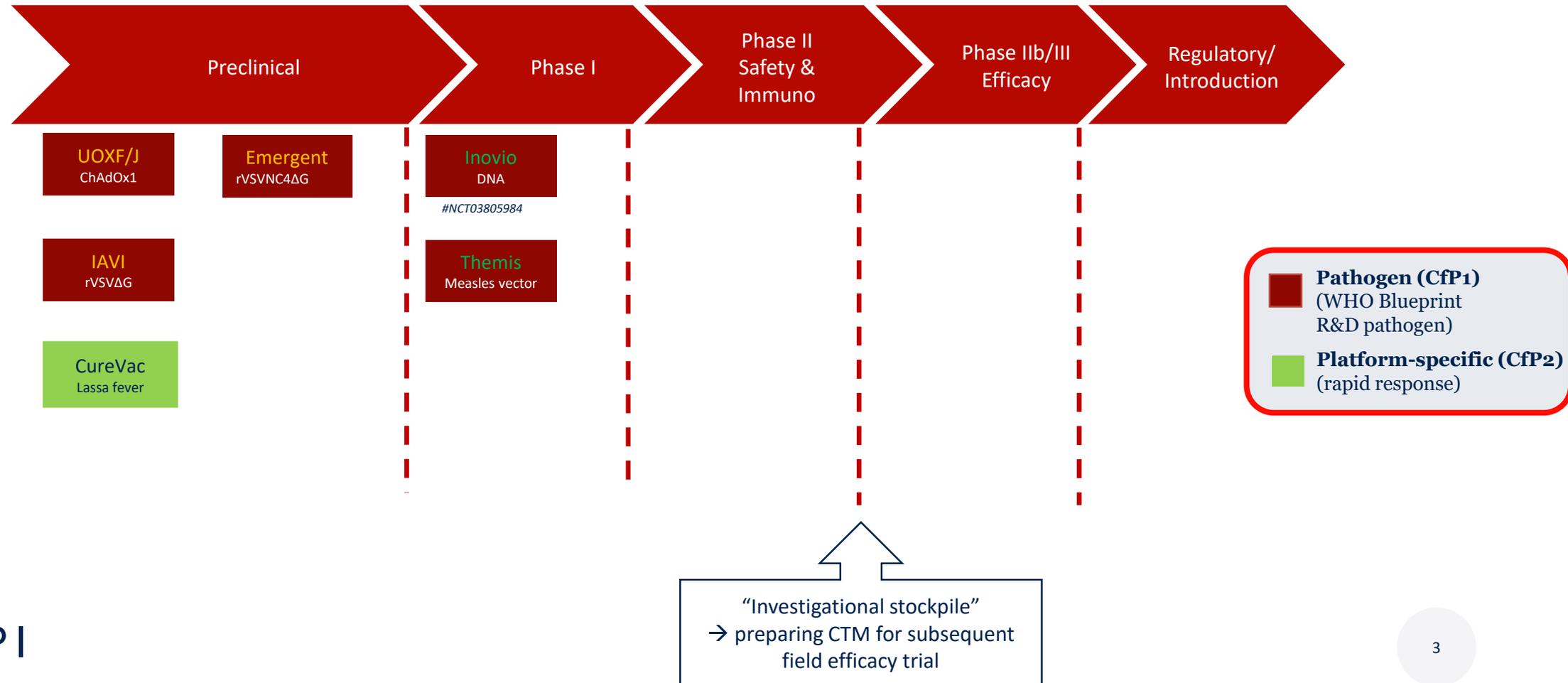


CEPI's Lassa Vaccine Development Program

- Aligns with WHO Blueprint R&D Roadmap
- Supports 6 Lassa vaccine candidates
 - First-in-human trials already underway
 - Anticipate there will be attrition as vaccine candidates progress
- Supports activities critical to vaccine development regardless of developer
 - Epidemiology (incidence/prevalence, capacity strengthening, trial planning, community mobilization)
 - Developing and validating assays & standards – first interim standards → WHO IS
 - Diagnostic test validation (for epidemiology and clinical trial endpoints)
 - Clinical trial site mapping and evaluation in endemic countries (trial planning)
 - Development of pharmacovigilance framework across development programs (trial execution) and case definitions (e.g. SNHL)

CEPI's Development Portfolio [Lassa]

Current Status (as of January 2020)



Epi Study to Inform Clinical Trial Design

Randomised controlled field efficacy trial:

- LF Incidence
 - Depending on vaccine efficacy (50%, 70%, 90% ???), approx. 19 to 360 confirmed cases will be necessary [Ira Longini]
 - Depending on incidence (1%? or 0.5%? or even lower?), this may require between a few thousands to 10,000s of subjects
- Role of seropositivity?
- Risk factors → inclusion (exclusion) criteria to recruit populations at highest risk
- Case definitions: test and revise case definitions for LF as well as for disease severity
- Operational methods: recruitment strategy? Follow-up strategy? Community engagement, etc.

Targeted Lassa Epidemiology Studies

2 pivotal questions:

- LF incidence?
- Role of seropositivity?

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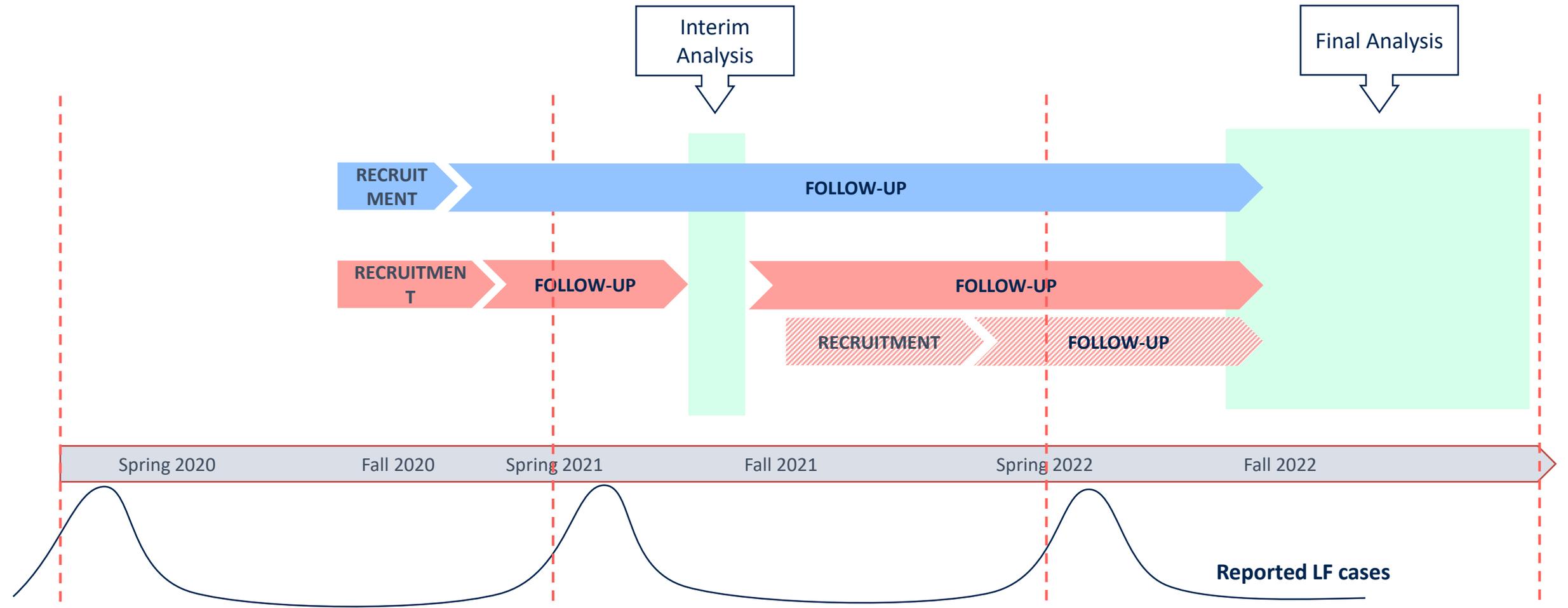
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- **Sero-incidence cohort**: estimate incident infections / country level
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Further aims / objectives:

- Incidence / prevalence in subgroups
 - ✓ Age, season, clade, site, etc.
- Risk factors for infection and disease
- Clinical course and outcome of LF illness (incl. SNHL)
- Frequency of co-infection with malaria parasites
- Capacity strengthening to conduct clinical trials in endemic areas

Prospective Lassa Epidemiology Study



Clinical Trial Site Mapping

CEPI identified & evaluated clinical trial sites in endemic countries in West Africa

- A total of $n=37$ sites suitable for clinical vaccine trials have been identified in Lassa-endemic countries
- State of readiness: Sites have been visited and evaluated based on a detailed questionnaire (ICON Government and Public Health Solutions, GPHS) → strengths and weaknesses → areas for capacity building
- Some of these sites are part of CEPI's multi country Lassa epidemiology study starting within the next months
- Site mapping report available



CEPI