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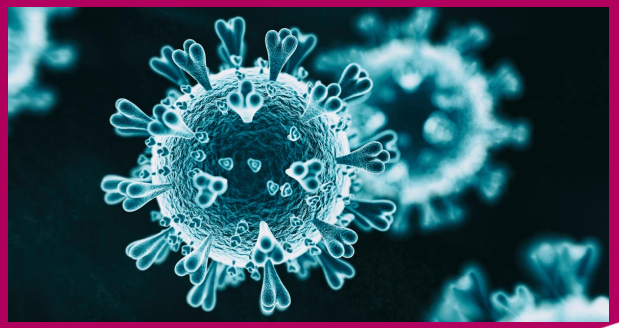
Translating Science to Medicine

Opening Safely in the Face of a Global Pandemic

Sarah K. Peters

November 17, 2020



Discussion Topics

- The effects of the SARS-CoV-2 virus and associated COVID-19 pandemic on Celerion clinics
- Response of Celerion bioanalytical laboratory
- Validated SARS-CoV-2 RT-PCR assay
- Implementation of PCR testing to safely resume Celerion clinic activities
- Development and validation of an extraction-free RT-PCR assay
- Future efforts and areas of focus to support drug programs and Celerion clinics

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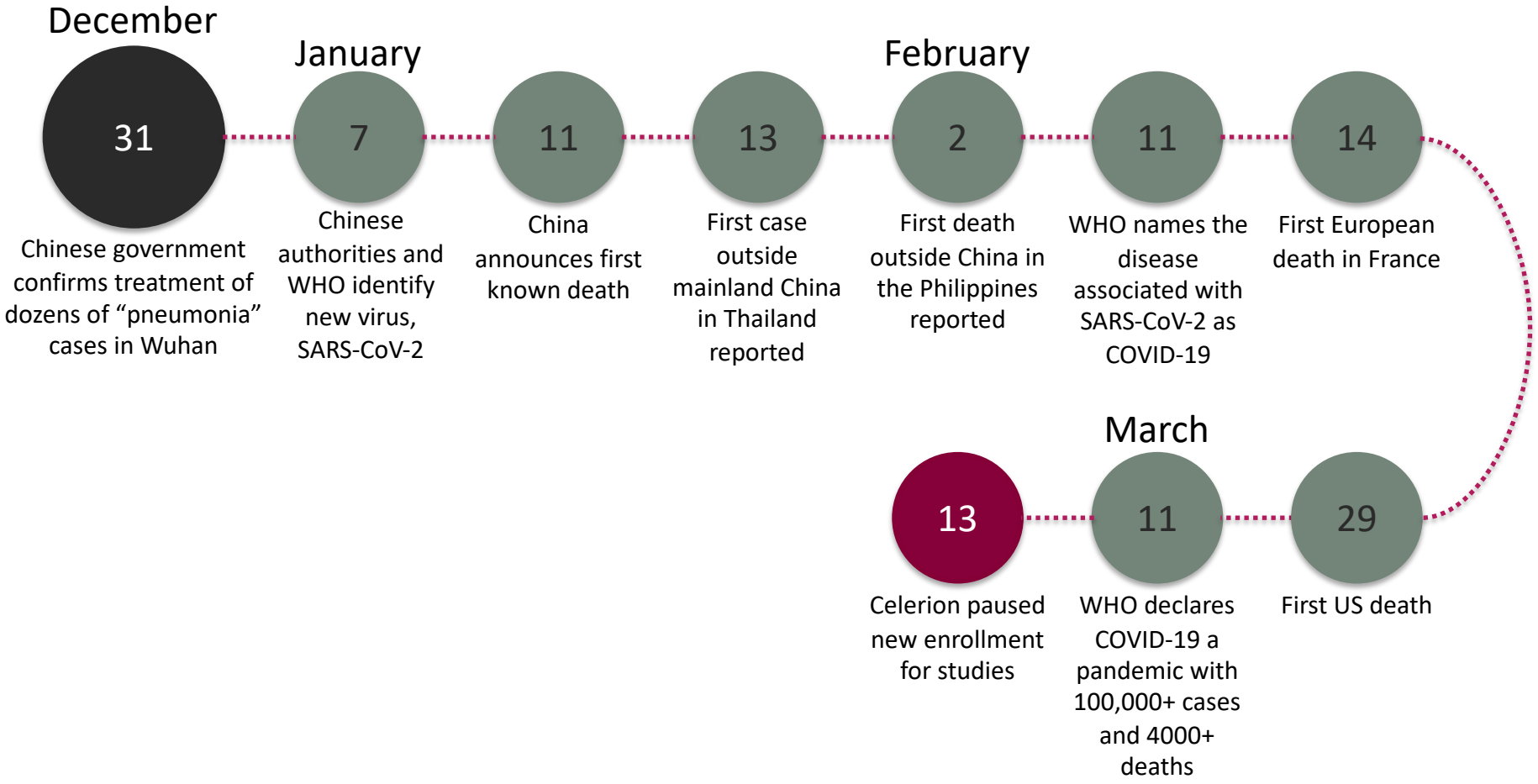
Timeline



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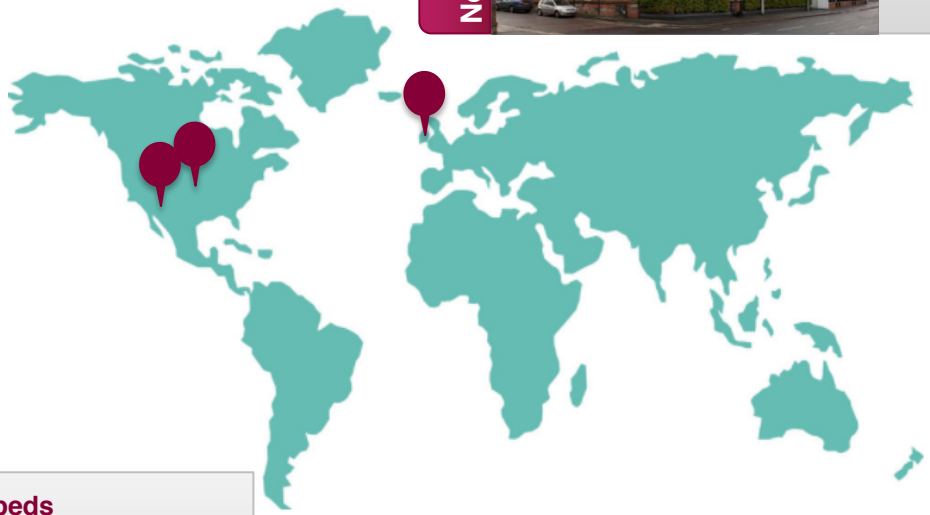
Celerion Clinical Sites

Lincoln, NE

- 200 beds
- 50,000 square feet
- 40 years of operation
- 364 employees

Belfast, Northern Ireland

- 78 beds
- 29,000 square feet
- 20 years of operation
- 87 employees



Phoenix, AZ

- 300 beds
- 105,000 square feet
- State-of-the-art purpose built facility opened in 2008
- 259 employees

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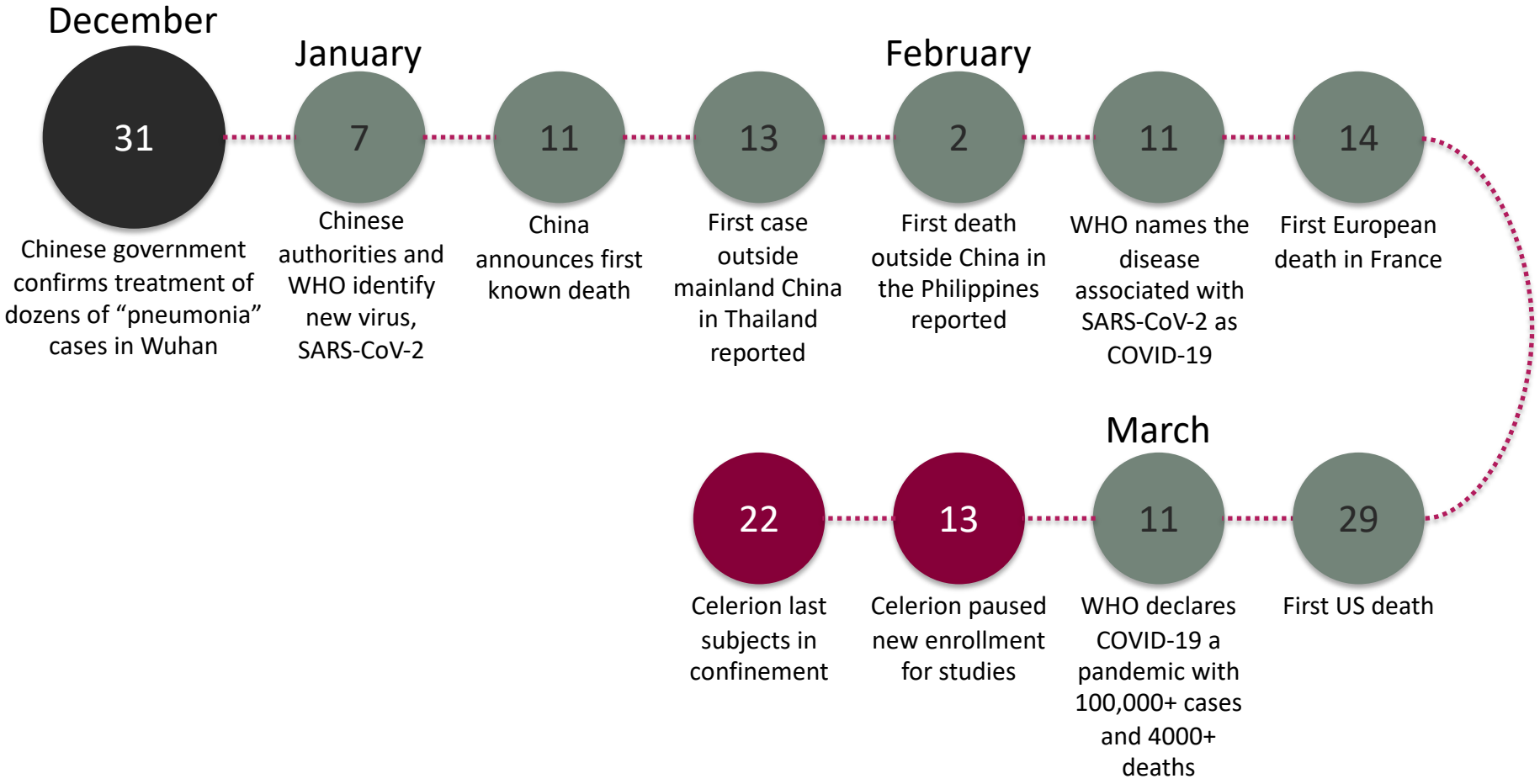
New Enrollment Paused

- ~450 participants on studies at this time, across all clinical sites
  - Not all were confined
  - Many were coming back for return visits
- Each study sponsor was consulted and adjustments to ongoing studies made wherever possible
  - Began conducting return visits remotely when possible

Timeline



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Last Subjects in Confinement

- PPE and testing were scarce as hospitals and other health care facilities required additional materials
  - Celerion clinics made the ethical decision to pause confinement operations
- Each study was discussed sponsor by sponsor to determine the best path forward
- Clinic staff had to rapidly adapt to ensure drug programs could continue without confinement
  - Adopted virtual visits whenever possible
  - Drive-by PK sampling in the parking lot

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SARS-CoV-2 Testing

- Celerion was in a fortunate position with both clinical sites and bioanalytical labs as part of the same company and even the same facility in Lincoln, Nebraska, USA
- BIO lab immediately started working to develop an RT-PCR assay to help keep the drug development programs moving forward safely

Lincoln, Nebraska, USA

- 30,000 sq. ft. (2,300 sq. m.)
- Over 40 years of operation
- 101 employees
  - LC-MS/MS (30 Systems) & ICP/M
  - Ligand Binding Services
  - Immunogenicity testing
  - Functional cell-based assays including Flow Cytometry
  - Human mass balance
  - Clinical biomarkers
  - PCR Analysis

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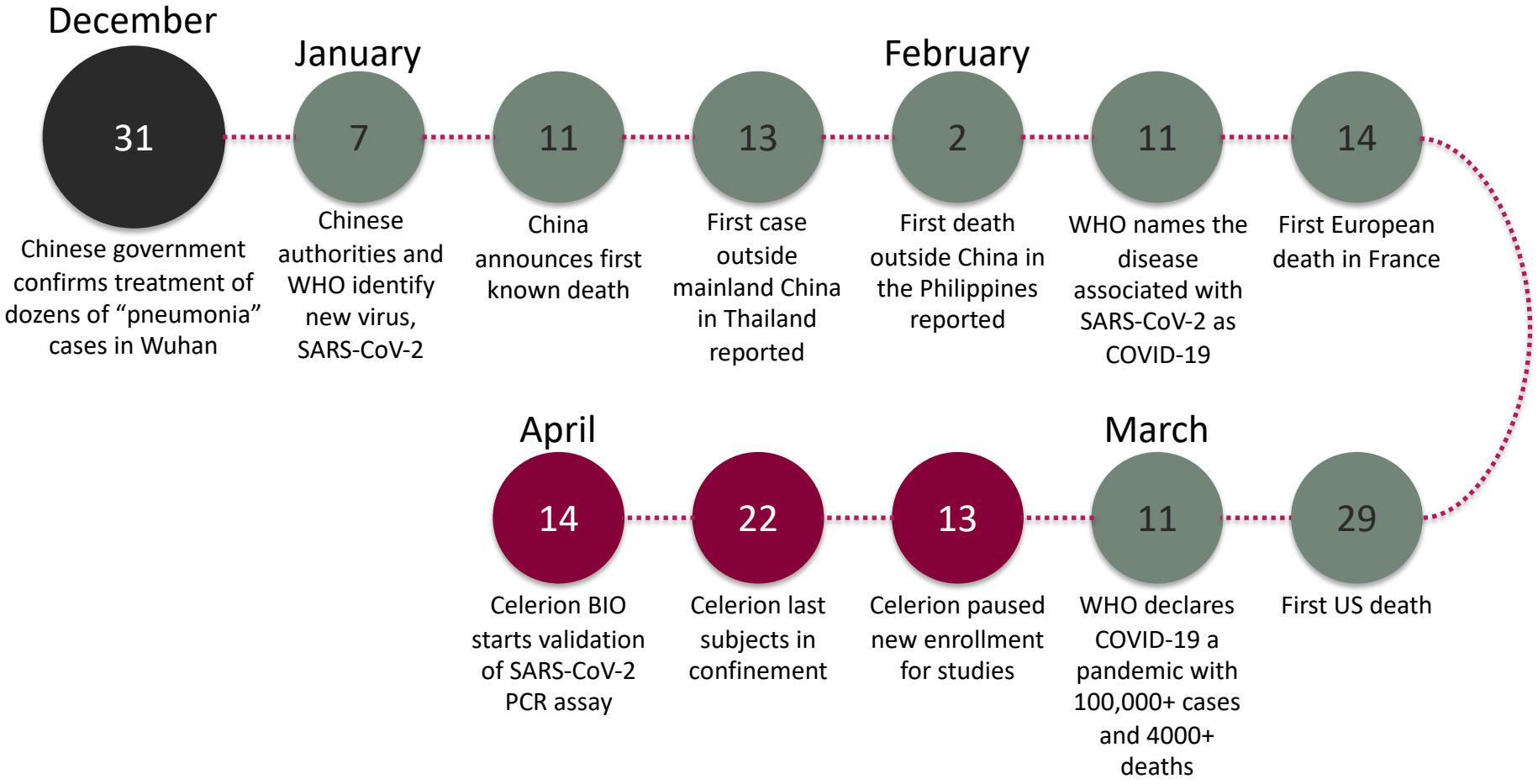
Timeline



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SARS-Cov-2 RT-PCR Assay

- Method based on the CDC's published method
  - Total nucleic acid (TNA) isolated and purified from nasopharyngeal (NG) swabs
  - 2 probes corresponding to 2 regions of the virus nucleocapsid (N) gene, N1 and N2
  - 1 probe to detect the human RNase P gene (RP)
- Modified extraction method
- Optimized master mix
- Validation based on CDC guidelines

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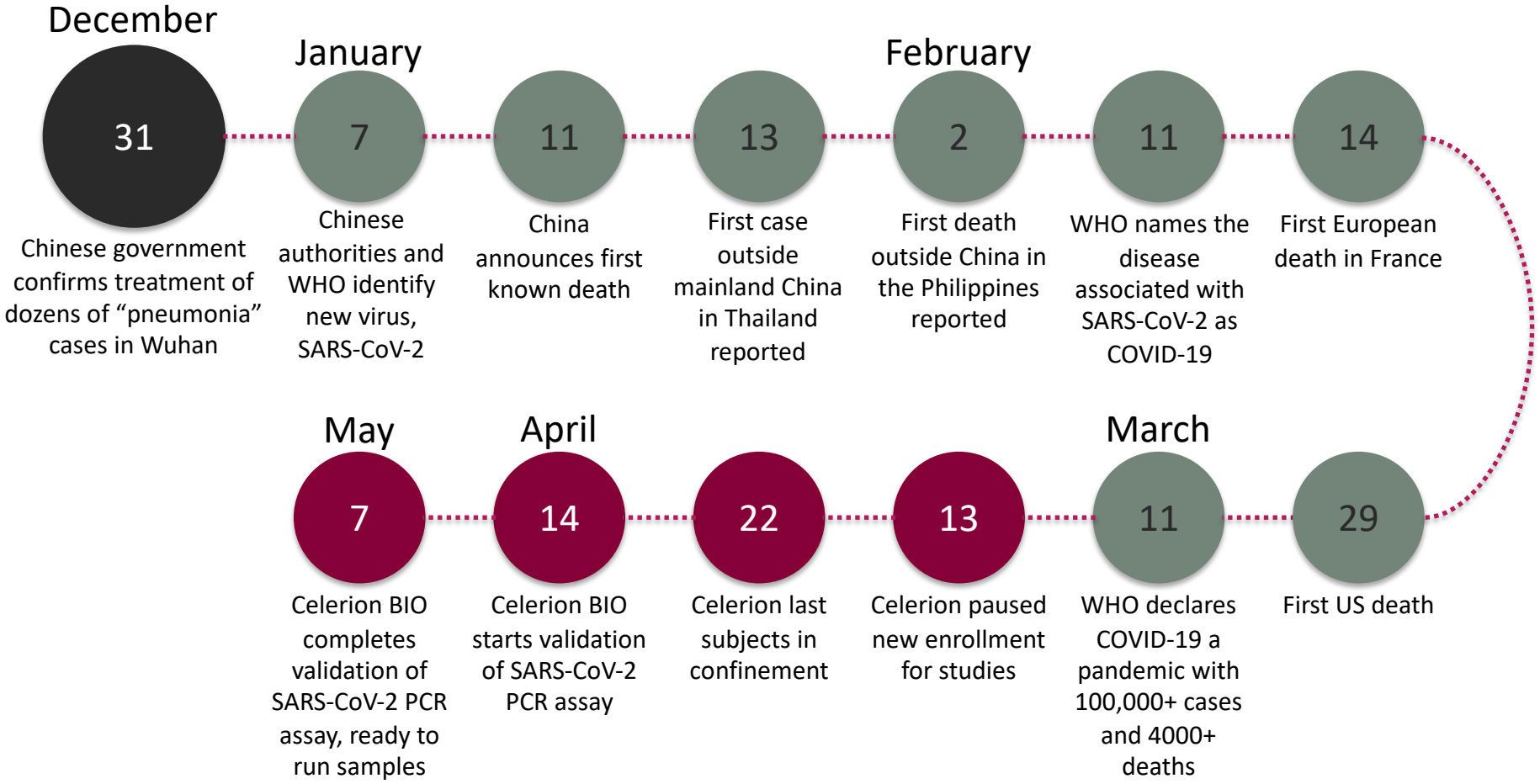
Resuming Clinic Activities

- Setup employee testing schedule
  - Every 14 days, more frequent if track and trace requires
- Complete risk assessments based on local health department, CDC, and FDA regulations
  - Update cleaning/disinfecting protocols
  - Obtain appropriate employee PPE once global/local supply chains stabilized
  - Reconfigured clinic spacing to allow for appropriate social distancing
- Communicate plans with sponsors
  - Studies with vulnerable populations and immunosuppressant drugs remain paused

Timeline



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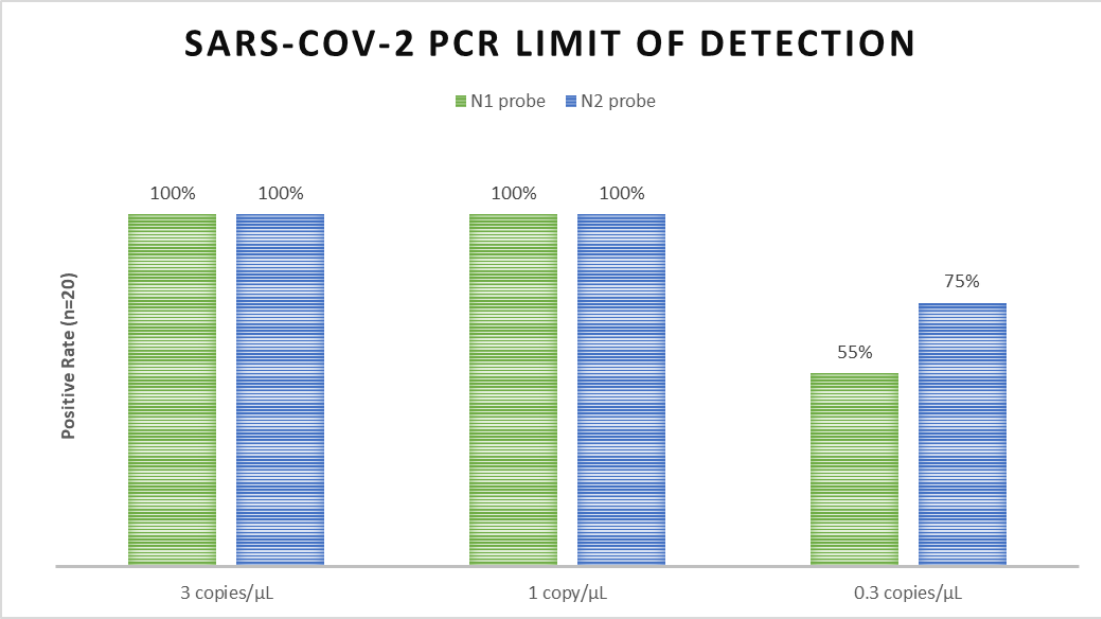
SARS-Cov-2 N Gene RT-PCR Assay

- Validated method
  - 1 copy/μL sensitivity



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SARS-Cov-2 N Gene RT-PCR Assay

- Validated method
  - 1 copy/μL sensitivity
  - Specimen stability in deactivation medium for 72 hours at 5°C
  - 100% assay reproducibility
    - Within-assay, between-assay, and between-operator
  - 6 – 8 hour turnaround for results

Detector N1	Detector N2	Detector RP	Result Interpretation	Report
+	+	+	2019-nCoV Detected	Positive 2019-nCoV
+	+	-		
+	-	+	Inconclusive Result	Inconclusive
-	+	+		
+	-	-		
-	+	-		
-	-	+	2019-nCoV Not Detected	Not Detected
-	-	-	Invalid Result	Invalid

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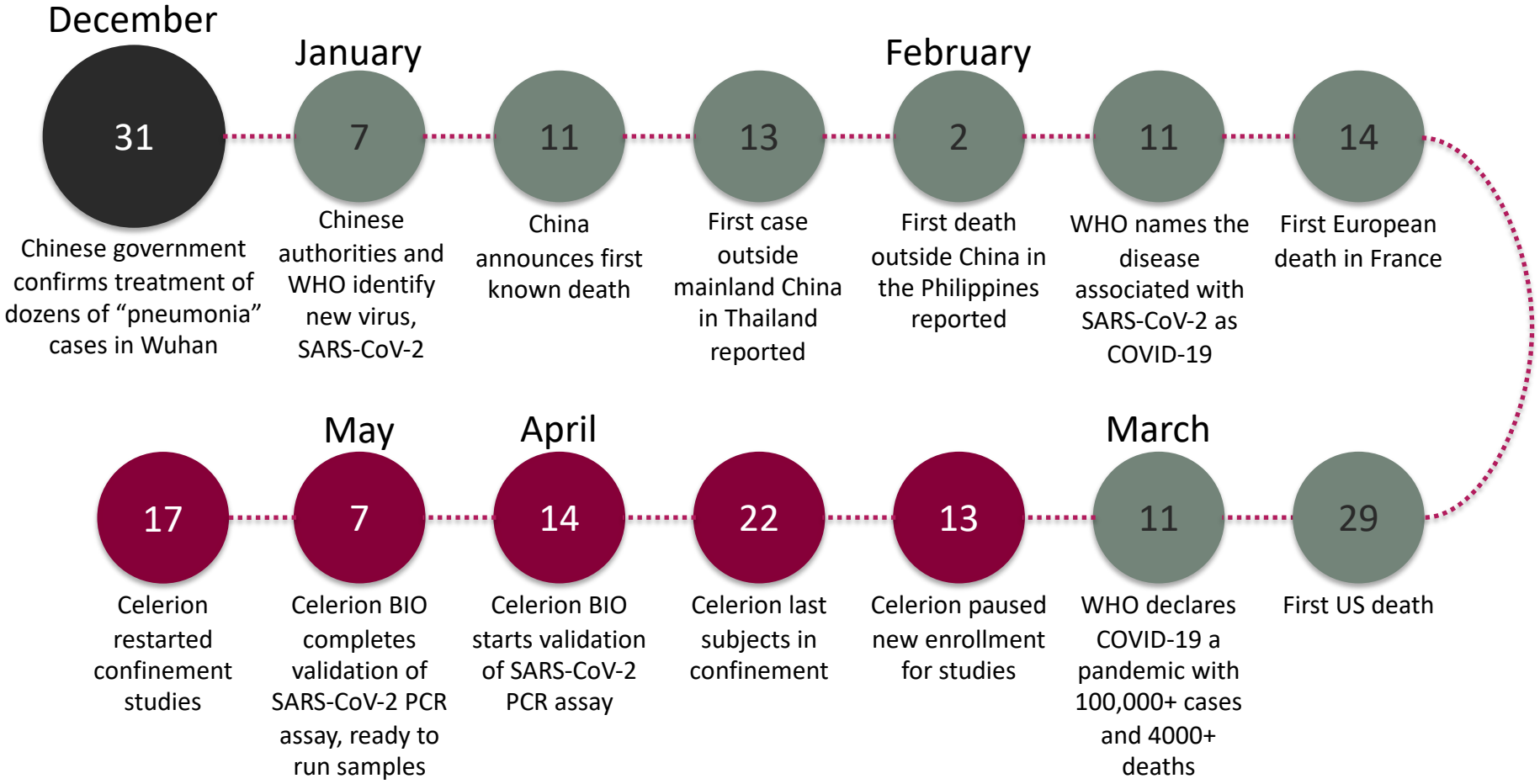
Timeline



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Extraction-Free RT-PCR Assay

- Looked to optimize efficiencies as clinical operations increased
  - Participants have NG swab at their screening visit and remain sequestered on-site or in a nearby hotel until a negative result is obtained
  - Participants placed on study and tested at least every 10 days while on study
  - BIO lab was running samples 24 hours a day, 7 days a week
  - Target: swabbing, shipping, and testing in the same day
- Extraction-free methodology poses challenges due to PCR inhibitors in the collection media
  - Evaluated different collection medias: live virus and deactivation
  - Increase sample volume
  - Test dilutions or adding reagents

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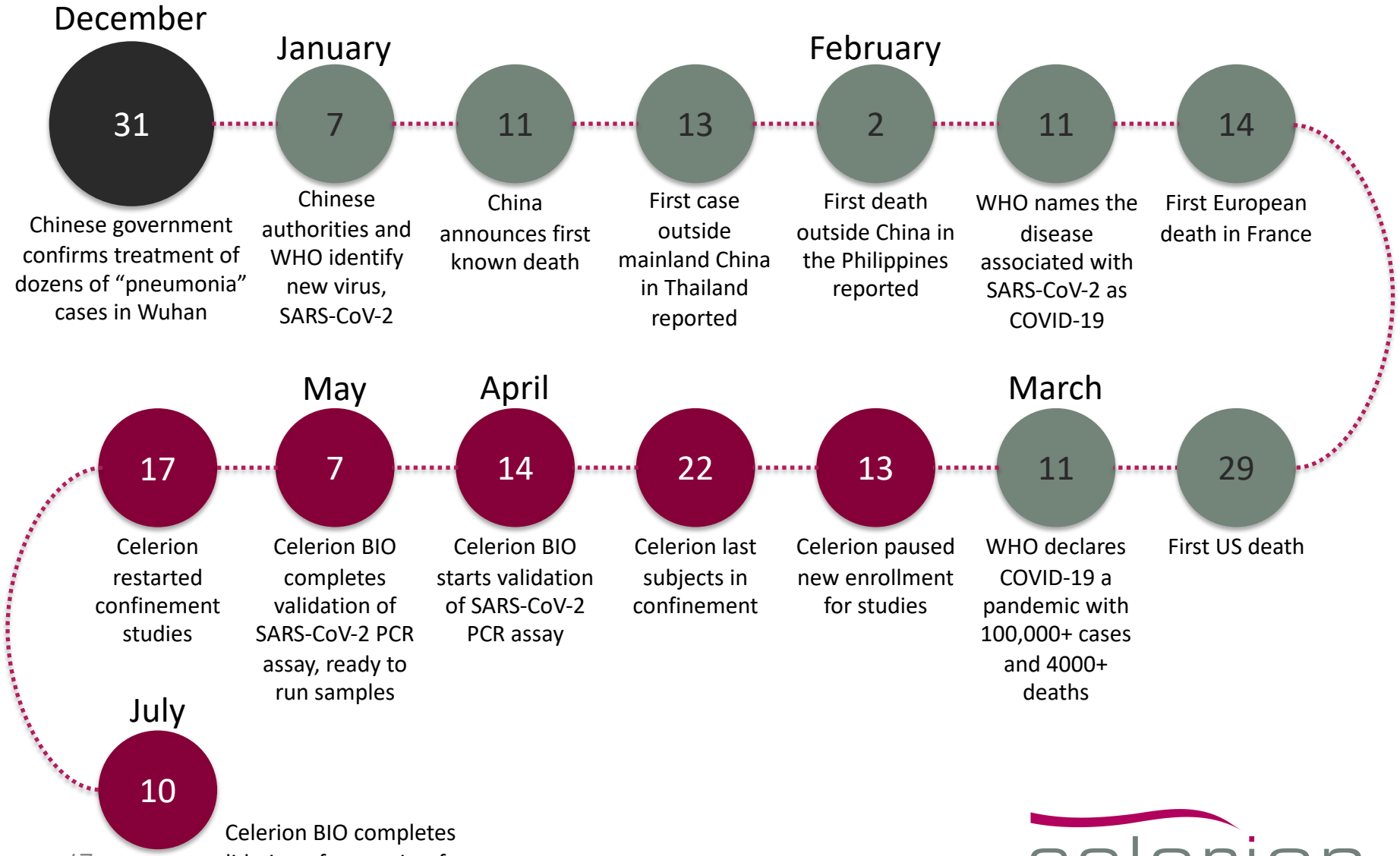
Timeline



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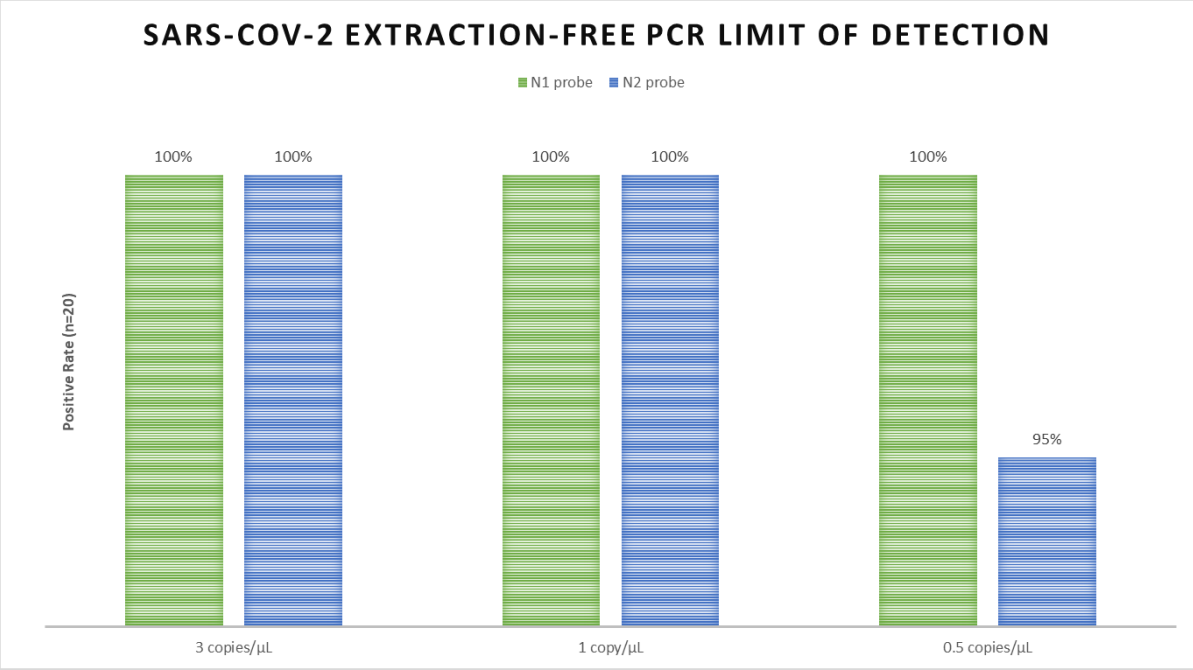
Extraction-Free RT-PCR Assay

- Validated extraction-free method
  - 0.5 copies/μL sensitivity



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Extraction-Free RT-PCR Assay

- Validated extraction-free method
  - 0.5 copies/μL sensitivity
  - 100% assay reproducibility
    - Within-assay, between-assay, and between-operator
  - 3 hour turnaround for results
  - Utilizes live virus collection media
- Expanded bioanalytical lab to the Phoenix facility for on-site testing
  - Remove the delay in obtaining results due to sample shipment

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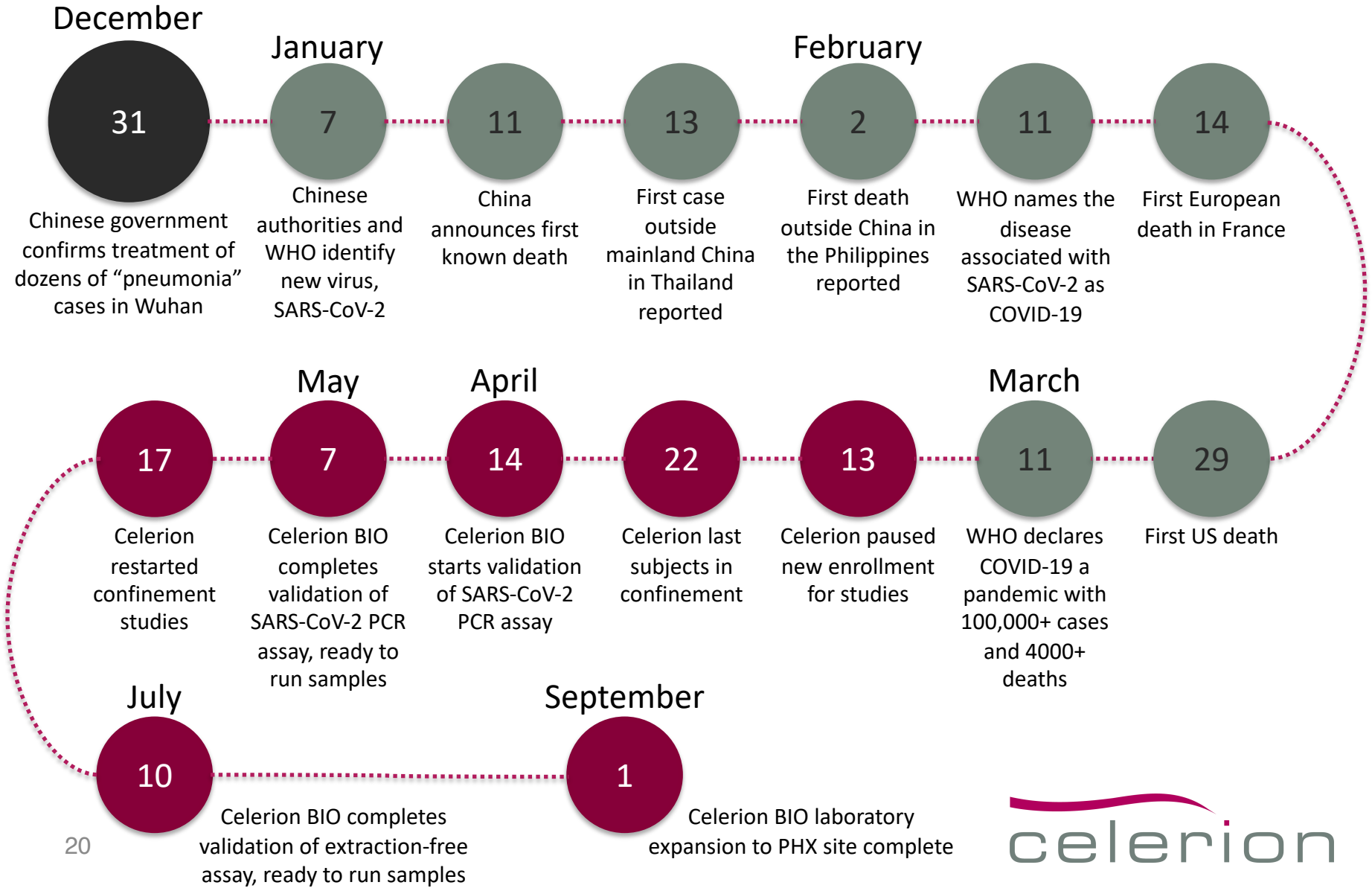
Timeline



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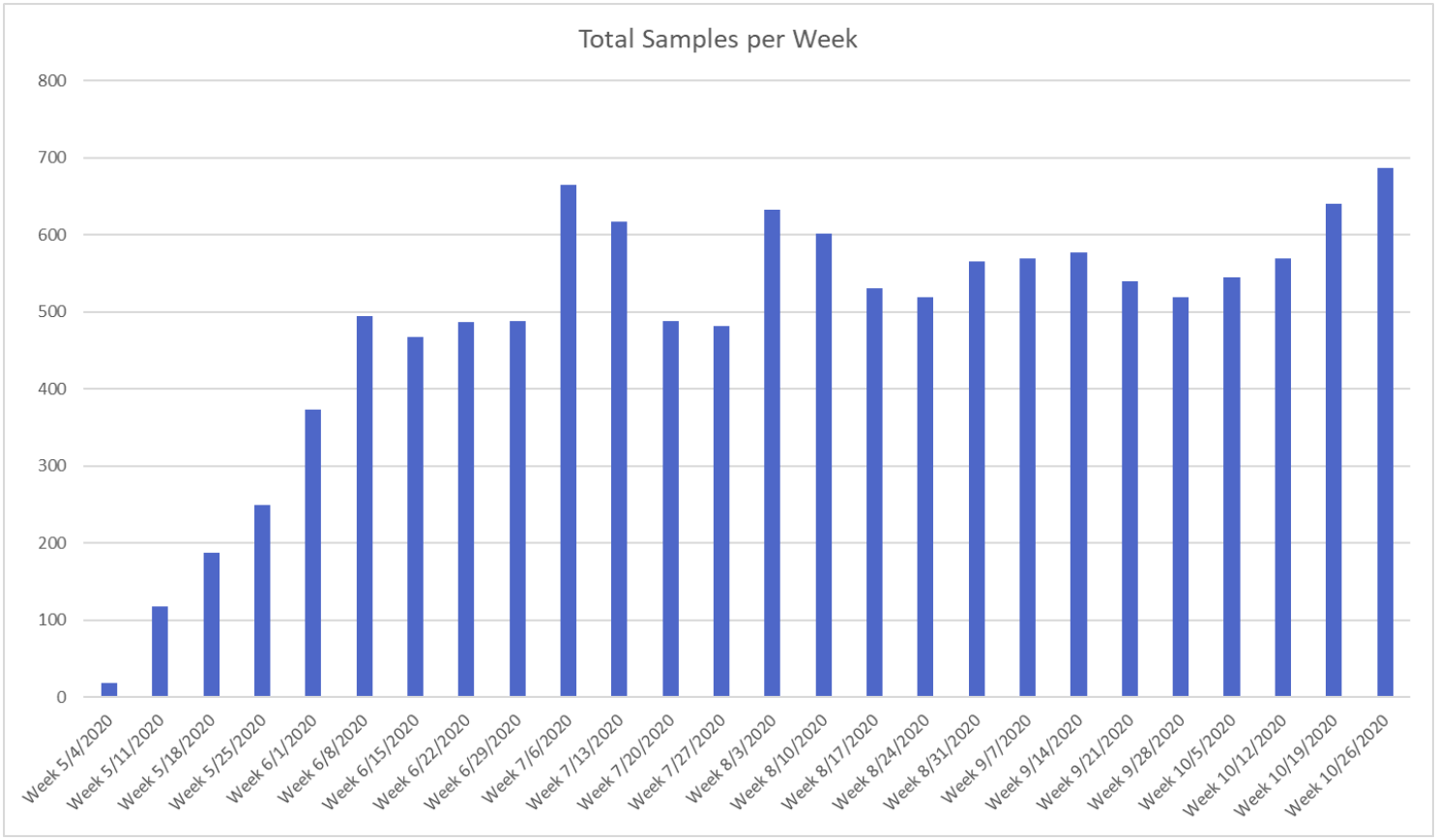
Testing Notes

- Analyzed 12,629 samples as of 31-Oct-2020



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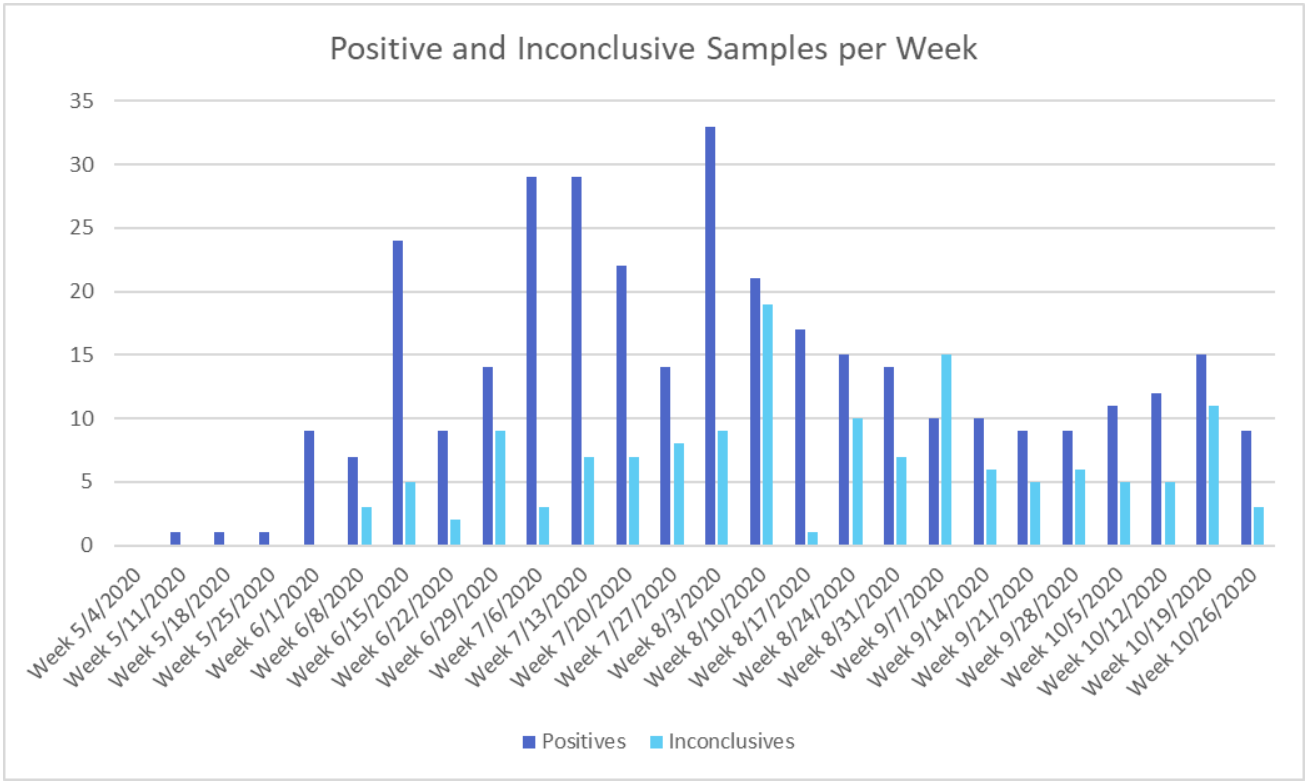
Testing Notes

- Analyzed 12,629 samples as of 31-Oct-2020
  - 345 positive samples, 2.73% positive rate



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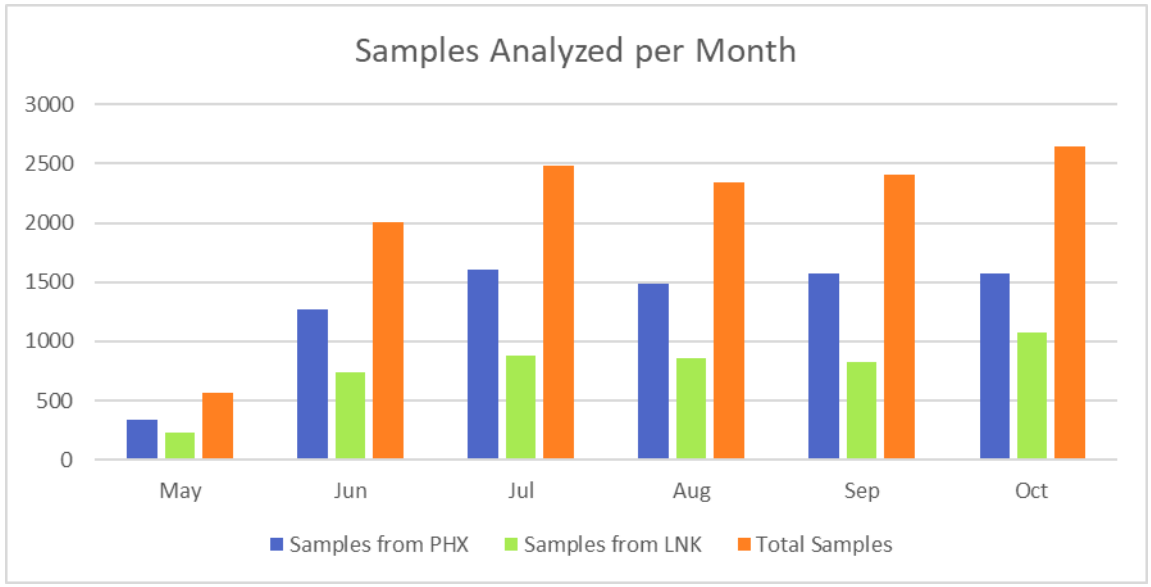
Testing Notes

- Analyzed 12,629 samples as of 31-Oct-2020
  - 345 positive samples, 2.73% positive rate
- Averaging ~520 samples per week since confinements resumed



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Future Efforts and Areas of Focus

- Update procedures to include rapid results/point of care testing
  - Evaluate sensitivity and the timeline for when a negative point of care test can become infectious
- Develop a saliva RT-PCR assay for less invasive sample collection
- Celerion is funding and conduction our own clinical trial
  - One of the parameters is evaluating viral load and virus quantitation
  - Enroll participants who fail screening due to a positive COVID-19 PCR test

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Acknowledgements

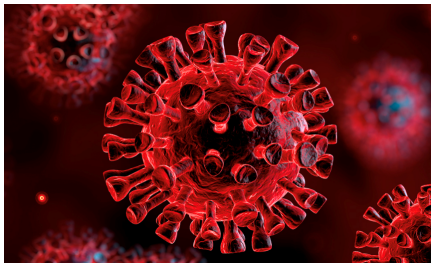
Celerion Clinical Team

- Phil Bach

Celerion BIO Team

- Adam Heiden
- Dave Lueckenhoff
- Anamica Muruganandham
- Tim Sangster

Questions?



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