

Monkey Vax Study

July 12th, 2022

PI :

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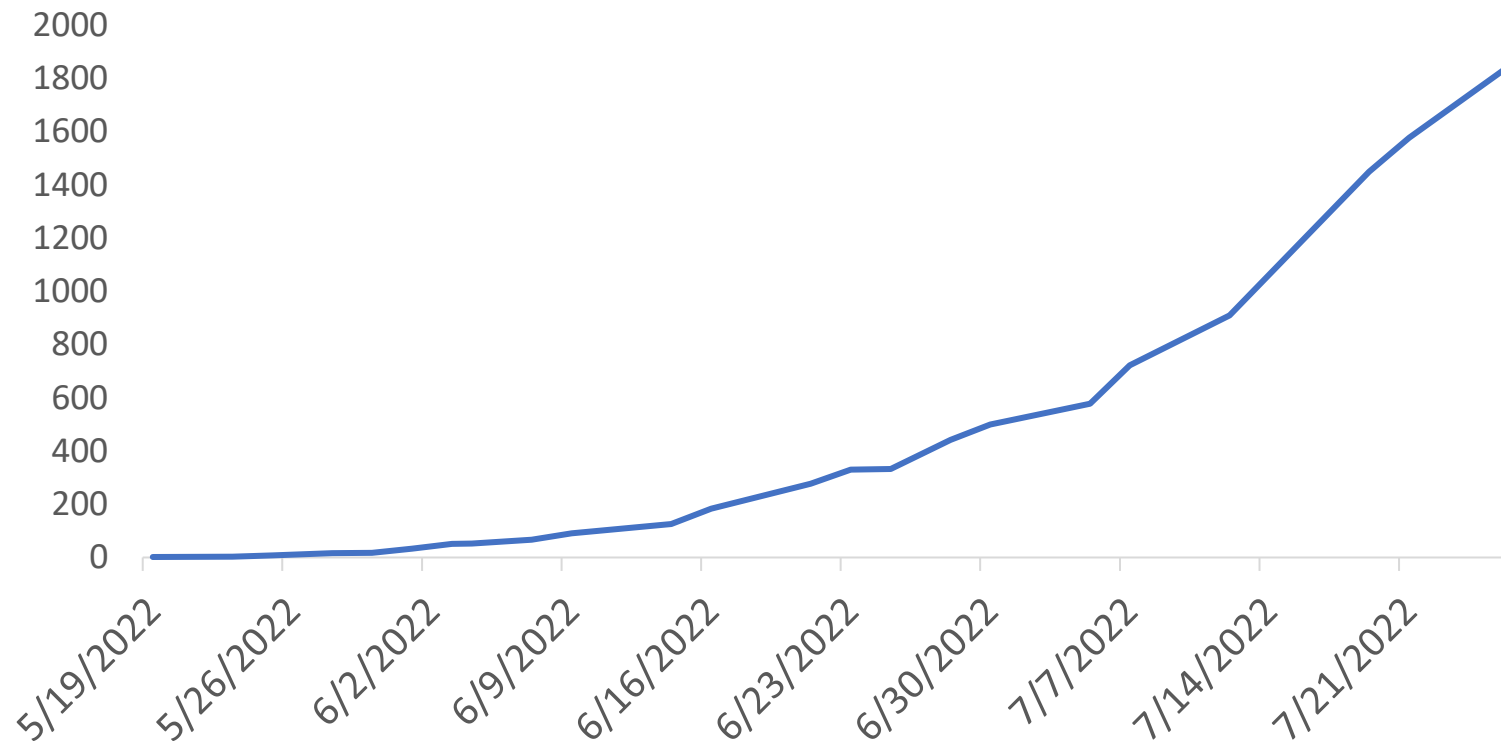
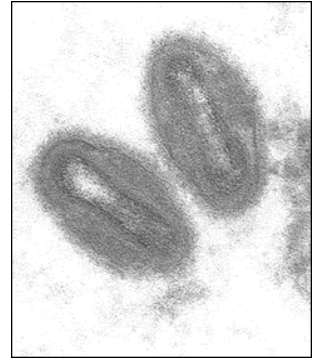
Co-PIs

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Monkeypox in France

- First case on May, 19th
- End of July: 1 846 cases, Paris area ++



Monkeypox case definitions (July 8th)

Case	Definition
Confirmed = positive PCR	MKP specific : qPCR or RT-PCR positive Orthopox virus : qPCR Positive ± partial sequencing
Suspect = Clinical signs	Vesicular rash (skin or mucosal) compatible with Monkeypox ± Fever (38°C) ± Lymphadenopathies ± Coryza
Possible = Suspected AND Exposure at risk	≥ 1 of the following exposure at risk: <ul style="list-style-type: none">• Back from endemic countries (Africa)• Multiple sexual partners• Part of the MSM community
Probable = suspected AND Contact at risk	<ul style="list-style-type: none">• Any unprotected physical contact (direct face to face, direct contact with skin with lesions or fluids from a probable or suspected case, or shared hygienic material• < 2m for > 3 h with a probable case or suspected

Indication of MVA-BN (Imvanex®) in France

- Since May, 20th: **post**-exposure prophylaxis to any individual with exposure at risk
- Since July, 7th : **pre**-exposure prophylaxis to
 - MSM with multiple sexual partners
 - Transgender with multiple sexual partners
 - Sex workers
 - Professionals working in place with multiple sexual intercoursess
- Schedule
 - 1 dose if already vaccinated during childhood (born before 1980)
 - 2 doses if born after 1980
 - 3 doses if immunocompromized (28 days apart)

I-REIVAC : The Innovative Clinical Research Network in Vaccinology

- Part of F-CRIN, managed by Inserm
- Network of 33 Investigating centers + biobanking capacity + 11 research laboratories in immunology.
- With strong links with ANRS|MIE
 - Participates in scientific boards
 - Participates in strategic decisions
 - Support and fund in part I-Reivac infrastructure
- Committed to develop European Clinical research

Monkey Vax Study

Main objective

Measure the PEP failure using MVA vaccine after 1 dose

Primary outcome

Proportion of participants with positive monkeypox PCR within 28 days
(in blood, urine, skin lesion or upper respiratory tract)

Secondary objectives and outcomes

Objectives	Outcomes
Immunogenicity	Humoral response (serology and neutralizing) at D_0 , D_7 , D_{14} , M_1 , M_2 , M_3
Factors associated with failure	Time from exposure to vaccination (<4d, 4-10d, > 10d) Age, comorbidities
Clinical presentation	Skin lesion and symptoms
Sexually transmitted co-infection at inclusion	HIV, HBV, HCV, Syphilis, Gono/Chlam at inclusion
Reactogenicity	Adverse events (local and general) after each dose
Vaccine hesitancy	Explore the « 3 Cs » components
Vaccine effectiveness	Comparison Not vaccinated vs vaccinated
Transmission	Viral detection in upper respiratory, blood, urine, and if symptoms : skin and genital compartments
Cellular Immunity	Substudy (30 subjects)

Study Design

- Sponsor : Assistance Publique – Hôpitaux de Paris (AP-HP)
- Funding/support : French Ministry of Health & ANRS|MIE
- Cohort study in 10 hospitals across the country, 230 participants
- Inclusion criteria
 - Age 18+
 - Exposure at risk < 14 days, not vaccinated
OR
Vaccinated < 28 days
 - Signed consent form
- Exclusion criteria
 - Diagnosed with Monkeypox
 - Contraindication to vaccine

Study Design

	Inclusion	Follow-up					
Visit	V1	V2	V3	V4	V5	V6	VS
Not vaccinated : D0 = inclusion day Already vaccinated : D0 = day of vaccination		7 ± 3 days*	14 ± 3 days*	28 ± 3 days	43 ± 3 days	3 months ± 1 wk	Symptoms
Eligibility criteria	R						
Information and consent	R						
Data collection	SOC	SOC	SOC	SOC	R	R	SOC
Physical exam	SOC	SOC	SOC	SOC	R	R	SOC
Samples							
Blood	R+ STI	R	R	R	R	R	SOC
Throat	R	R	R	R	R	R	SOC
Urine	R	R	R	R	R	R	SOC
Skin + Genital							SOC

SOC : Standard of Care. R : research

*not applicable if already vaccinated before

Sample size calculation (main objective)

- **Estimated failure rate: 0.2**

Upper limit CI at 97.5%	N Total (meeting endpoint)	N failure	Power
0.30	155	42	0.809
0.35	75	23	0.817
0.40	45	15	0.857
0.45	35	13	0.866
0.50	25	10	0.885

CORRESPONDENCE | 13 July 2022

A prospective national cohort evaluating ring MVA vaccination as post-exposure prophylaxis for monkeypox

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- Inclusions started on July 17th
- Discussions to expand to other countries
- Amendment to include participants with Pre-exposure vaccination

MPX outbreak: French research strategy coordinated by ANRS | MIE

- Define research priorities
- Making funding available (ANRS MPX call)
- Launch new studies (national & European & International level)
- **Launch nested studies with existing cohorts and/or clinical trials in MSM (Prep)**

The ongoing ANRS 174 Doxyvac study

- A randomized control study, evaluating 2 interventions among MSM with multiple sexual partners initiated in 2021
 - Doxycycline prophylaxis (syphilis or *C. trachomatis* infection)
 - Meningococcal B vaccine (Bexsero®) (*N. Gonorrhoeae* infection)
- Population :
 - 720 participants
 - HIV negative, MSM, high risk of HIV infection with inconsistent condom use
- The population enrolled in this trial eligible for **pre**-exposure prophylaxis MPX vaccination since July 7th in France
- Amendements to collect data on MKP vaccination and infection
- Comparison of MKP incidence rate in vaccinated vs unvaccinated

Thank you !

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Questions?

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