



Final stakeholder meeting WP11, 28th september

CHIMs in Inno4Vac: developments, achievements and challenges

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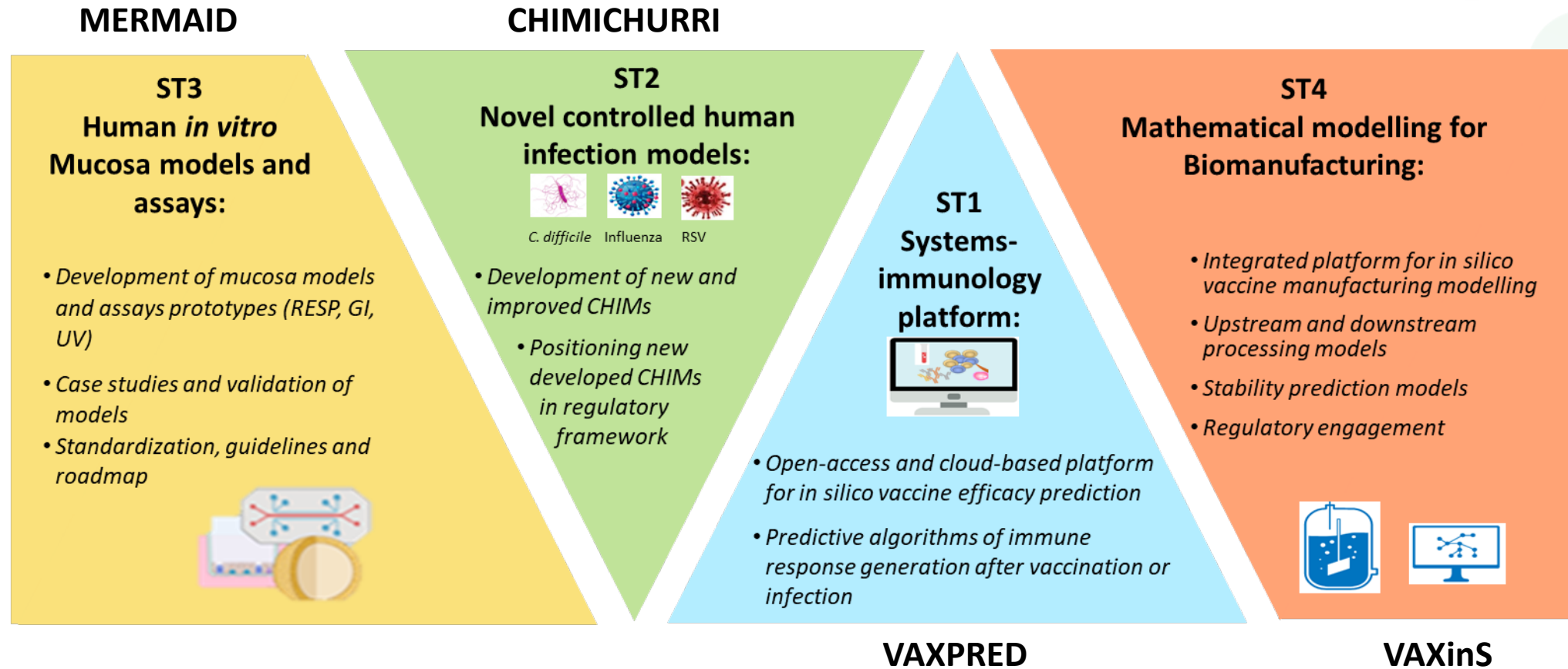
Inno4Vac partners

39 Partners from 11 countries



Inno4Vac Strategy

Accelerate and de-risk development of new vaccines

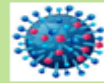


Inno4Vac ST2 - CHIMICHURRI

ST2 Novel controlled human infection models:



C. difficile



Influenza



RSV

- *Development of new and improved CHIMs*
- *Positioning new developed CHIMs in regulatory framework*

Clostridicum difficile - Developments

Establishment of production

- Strain selection
- Animal product free production
- According to GMP principles
- Formulated in capsules



Protocol development

- TCD protocol guided by non-toxicogenic strain study
- Establishment of new model



Clostridicum difficile - Achievements



Successfully established production of capsules containing spores

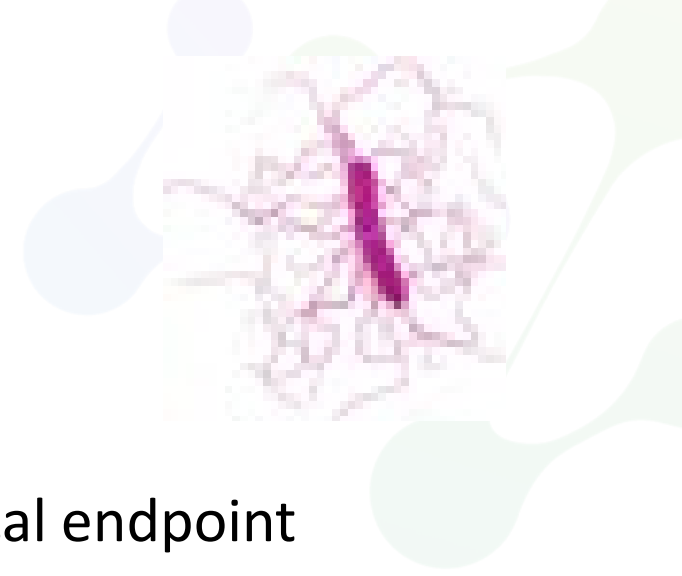
New model developed

With vancomycin pre-treatment 100% colonization, 20% clinical endpoint

Generally well-tolerated

All participants cleared colonization

Clostridicum difficile - Challenges



Low clinical attack rate despite successful colonization

→ Continuation with extended cohort to better understand clinical endpoint

Colonization with non-challenge strains

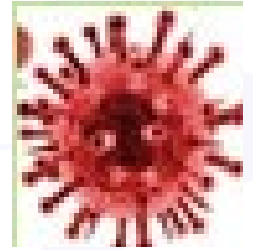
Risk of spread to bystanders → implementation of extensive cleaning procedures

RSV - Developments

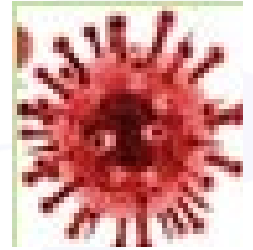
New model for RSV-B

Outpatient design

Not screened for pre-existing immunity



RSV - Achievements



Establishment of RSV-B model

Successful outpatient design

At medium dose infection rate of 74% and disease rate of 63%

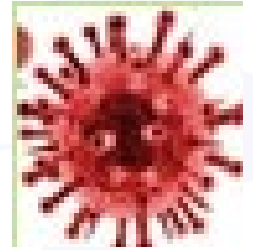
Well tolerated

Good attack rate despite not screening for background immunity

Article submitted to JID

Move to older adults at Imperial

RSV - Challenges

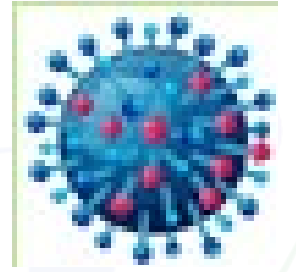


Conducted as outpatient

Bystander risk, need for bystander informed consent?

Practical issues: bedside preparation of challenge inoculum was needed

Influenza - Developments



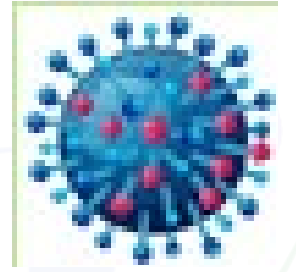
In patient design

Use of questionnaires to assess participant well-being

Development and production of challenge strain

- Workshop on strain selection
- Creation of IMPD
- Process of selection and characterisation

Influenza - Achievements

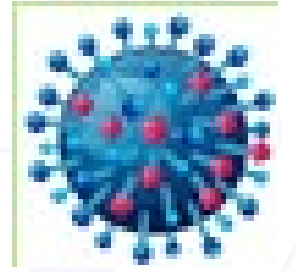


Successful development of IMPD and production

First participant successfully inoculated

Participant 2 and 3 scheduled for inoculation 29th September

Influenza - Challenges



In patient design: wellbeing of participants?

Biosafety questions regarding inpatient stay and possibilities for participants to get some air

Recruitment and enrollment: HAI<3 obstacle to enrollment, had to be amended to HAI <20

Time-consuming procedure of selection and production of strain

Conclusions

Successfully established 2 novel models and 3rd is in conduct

Successfully produced 3 different challenge agents

Significant hurdles:

- Production process
- Pre-existing immunological background
- Bystander risk
- In- vs outpatient



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