



INNO4VAC

*Innovations to accelerate vaccine
development and manufacture*

Workshop On Refining The Regulatory Context Of Controlled Human Infection Models

Panel discussion

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What are the critical requirements for a viral CHIM to be conducted as outpatient?
What are the consequences of not doing the CHIM outpatient?



Bystander risk: how to incorporate this into the safety assessment of the protocol and how to make sure that this is systematically assessed?



How do the production dossier and production processes of challenge agents fit into the new CTR regulations and requirements for IMPD's?

What if they don't fit – e.g. requirements are scientifically impossible or financially challenging?



What is the role of community and participant engagement in CHIM-development in Europe?