Famhp vaccine news

Vaccine Symposium

06.12.2019

Stéphanie MALI

famhp
federal agency for medicines and health products

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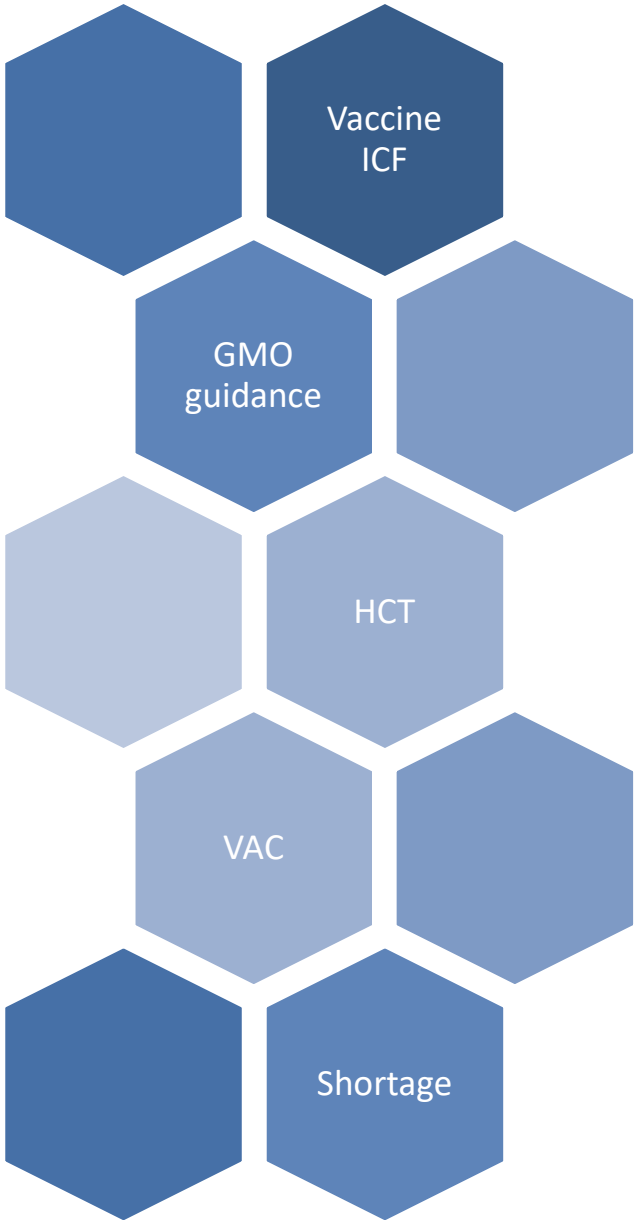
Introduction



Vaccine model informed consent

Project in collaboration with the Clinical Trial College

With the support of a dedicated working group EC, Sponsors, clinical trials sites)

Ensure vaccine specificities are included

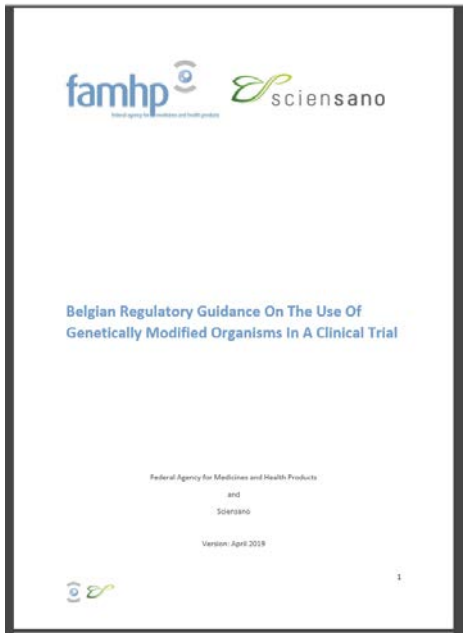
Create a shorter ICF form without compromising quality

Increase volunteer comprehension through:

- Increasing readability
- Implementation of visual aids
- Applying subject feedback

English ICF version by end of March 2020

Guidance on the use of GMO in clinical trials


famhp
sciensano
Belgian Regulatory Guidance On The Use Of Genetically Modified Organisms In A Clinical Trial
Federal Agency for Medicines and Health Products
and
Sciensano
Version: April 2019
1

Submission of applications for clinical trials with GMO medicinal products:

For the submission of applications for clinical trials with GMO medicinal products please follow the guidance document: Belgian Regulatory Guidance On The Use Of Genetically Modified Organisms In A Clinical Trial

A Questions and Answers document and an overview of the regulatory requirements in most of the EU countries are also available on the European Commission website by following this link.

→ Available on FAMHP and Sciensano website

And a review on regulatory framework

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Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Review

Clinical trials with GMO-containing vaccines in Europe: Status and regulatory framework

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ABSTRACT

Recombinant technology has revolutionised the way novel vaccines are developed and manufactured. The possibility to genetically modify micro-organisms to bring immunogenic material (antigens/epitopes) to the human (or animal) immune system to provoke an immune response, provides new hope to producing prophylactic vaccines against HIV, malaria and tuberculosis and emerging diseases. Regulatory requirements associated with the development of genetically-modified organism (GMO)-containing vaccines in Europe add an additional burden to the clinical trial application procedure and to the preparation and initiation of a clinical trial of such vaccines. Moreover, the GMO regulatory framework is complex and only partially harmonised across Europe, which may hamper multi-country clinical trials with GMO-containing vaccines. This paper provides an overview of clinical trial applications with GMO-containing vaccines in Europe and reviews the regulatory framework in countries where GMO-containing vaccine clinical trial authorisation (CTA) applications were submitted between 2004 and 2017.

Contents

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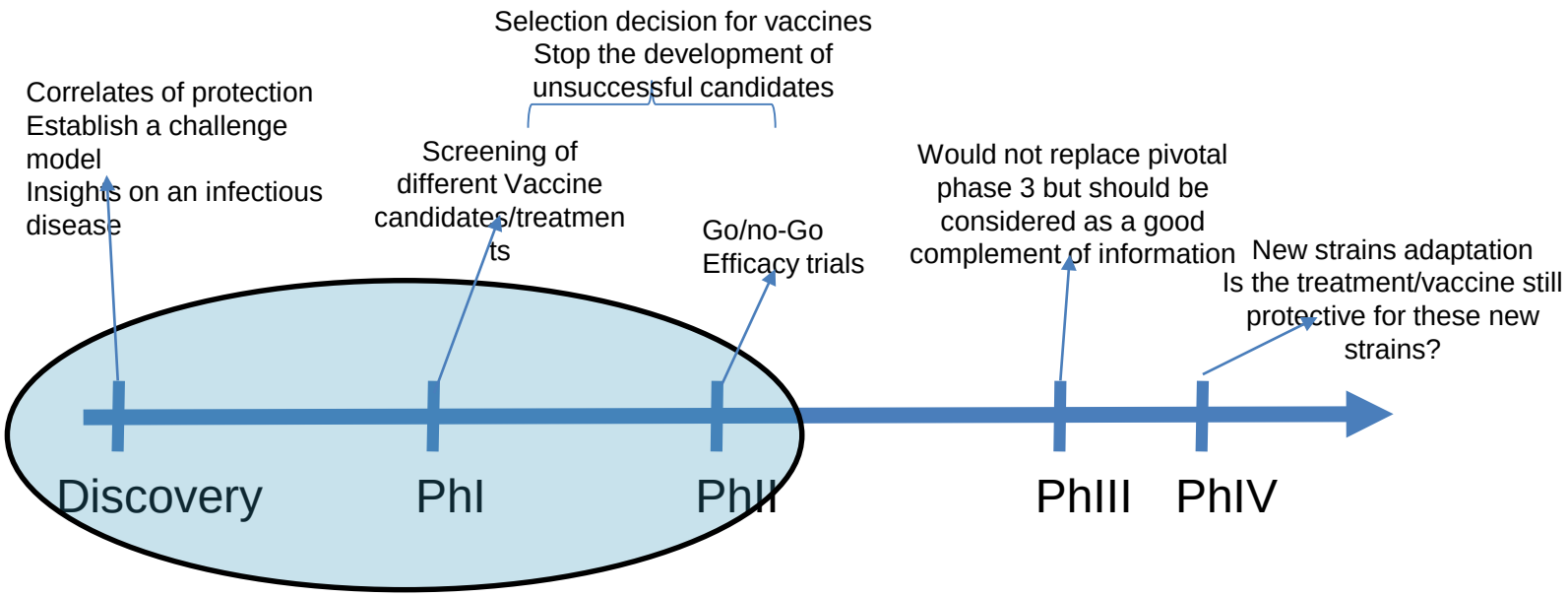
0264-410X/

Human Challenge trials

Clinical studies in which a limited number of trial participants are intentionally infected – i.e. challenged – with a pathogenic strain, being attenuated or not, in order to mimic the natural host-pathogen interaction



FAMHP position paper aims to clarify how to conduct CHI studies in Belgium, with the associated quality and safety requirements.

Vaccinovigilance Advisory Committee (VAC)

The VAC is a committee of **FAMHP**, **DG-POST**, created in **October 2018**

The aim of this workgroup is to address concerns:

- **identified from pharmacovigilance activities or**
- **raised by all stakeholders** and more specifically the public and health authorities

on the **safety** of **vaccines** through effective use of vaccine pharmacovigilance principles and methods.

The VAC is composed of **representatives** from various Belgian Public Health Institutions, Scientific committees and patient representatives

Shortage: Famhp approach

- Strengthening the procedure to track unavailability notifications
- Analysis of every unavailable product according to a decision tree showing the criticality of unavailability (duration, alternative, indication) → different measures can be taken:
    - replacement by an available alternative
    - import by firm or pharmacist
    - if no solution: task force

Shortage: vaccine considerations

- Most times few alternatives are available
- If global issue, import is not an option
- Major impact on public health
- Tenders vs others markets

⇒ Collaboration with the CSS/HGR to prepare proactive recommendations/prioritisation

⇒ Follow European Joint Action on Vaccination

Thank you for your attention

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