



Objectives



- Guide students through the Vaccine Development Process Map (<http://vaccinedevelopment.org.uk/index.html>).



- Provide an understanding of why it is critical to adhere to guidelines for vaccine development.
- Show one example of development that resulted in catastrophe. Then allow students to discover how it may have been avoided.

Understand. Do not memorize.



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Target Product Profile

1. Project Title
2. Target Antigens
3. Objective/Indication for use (usage scenario- emergency/reactive or prophylactic/ preparedness, risk/benefit profile, etc.)
4. Disease Prevention Claims (prevent/reduce, clinical signs/infection)
5. Target Species (the target species, and sub-category)
6. Minimal Age for Vaccination
7. Dosing Schedule (single/multiple dose, time between doses, booster requirements etc.)
8. Route of Administration (injectable - intramuscular/subcutaneous, non-injectable, oral delivery, etc.

5/10/2020

Vaccinology-Ausama

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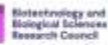
Development starts here. For new products, that is important. For development of existing product attributes, it is equally important.



Target Product Profile

9. Onset of Immunity
10. Duration of Immunity
11. Safety Claims (e.g. safe in pregnant animals, safety in lactation or lay)
12. Adverse Reactions (swelling at vaccination site, side effects, frequency, etc.)
13. Product stability and storage (shelf life, temperature requirements, preservatives, necessity/desirability/ability to stockpile etc.)
14. Withdrawal Period
15. Immunological Properties (mode of action)
16. Co-administration with other vaccines (interference with other vaccines etc.)

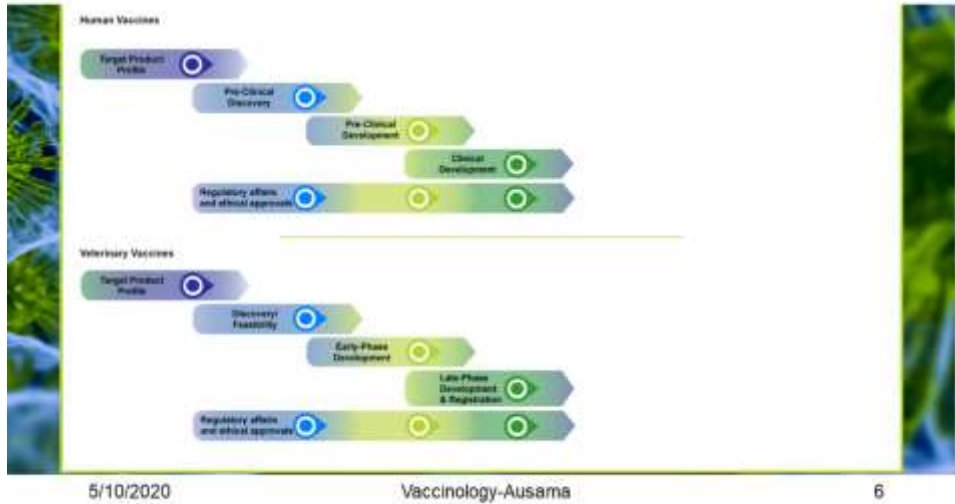
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Target Product Profile

17. Interaction with other medicinal products.
18. Presentation (liquid/lyophilized, mono-dose/multi-dose, dosage volume etc.)
19. Formulation (vial size, concentration, fill volume etc.)
20. Production (number of doses required over what period of time, ability to scale up/out, high/low volume supply, affordability etc.)
21. Registration Strategy (type of license)
22. Marketing attributes (Understanding the level of commercial interest, competitive advantage relative to competitor products, cost to produce versus anticipated sale price etc.)
23. Post marketing surveillance (monitoring of safety, protection of the target population, vaccine breakdowns, etc)

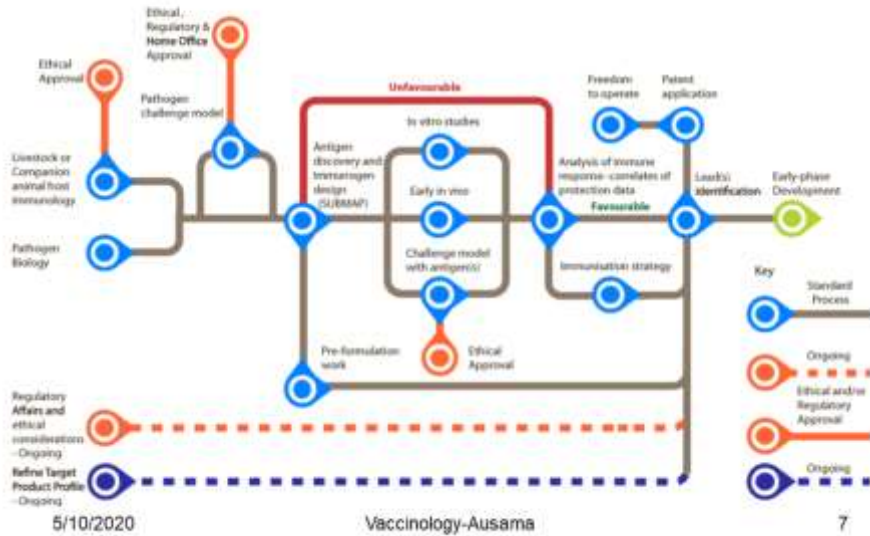
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There are clear differences between veterinary and human product development. Can you tell find out two?



Veterinary Vaccine: Discovery/Feasibility



I do not want you to remember the steps. All you need to do is go over the steps carefully and try to understand why each step is needed. When you are done, go to the website and click the “show bottlenecks” button. There you will discover how research and regulation go hand in hand.



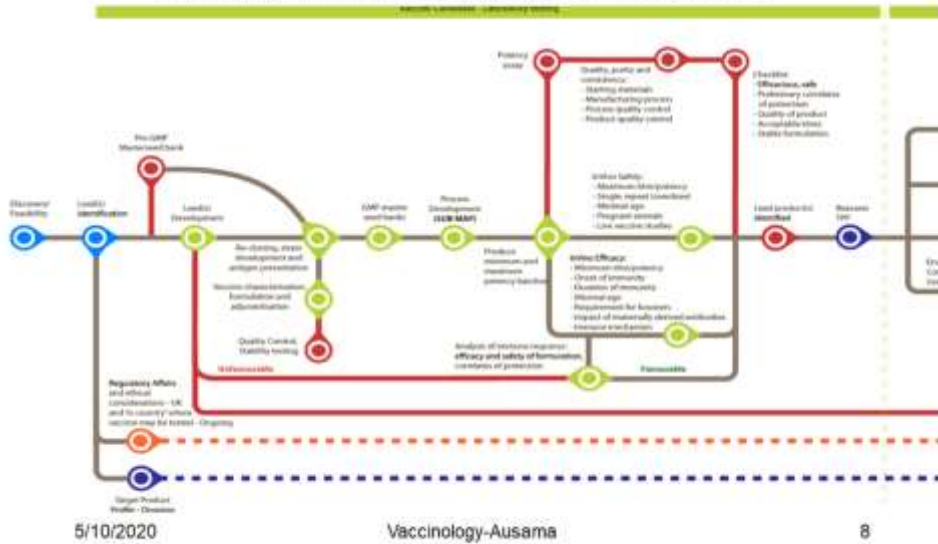
Biotechnology and Biological Sciences Research Council



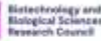
Vaccine Development Process Map



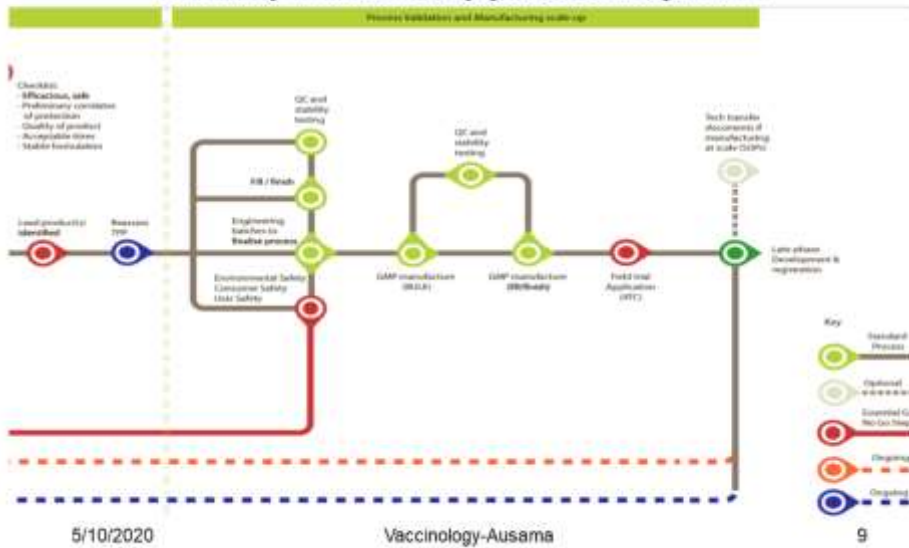
Veterinary Vaccine: Early-phase Development 1



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Veterinary Vaccine: Early-phase Development 2



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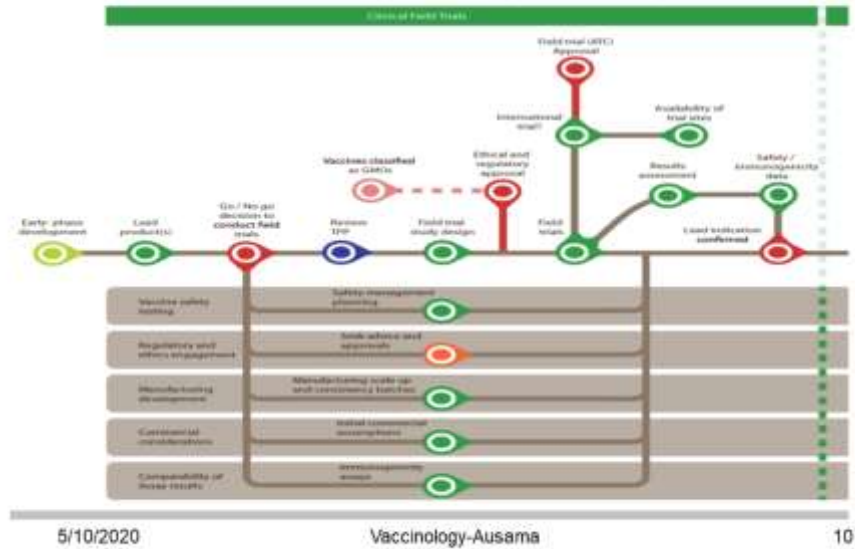
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Vaccine Development Process Map



Veterinary Vaccine: Late-phase Development and Registration 1



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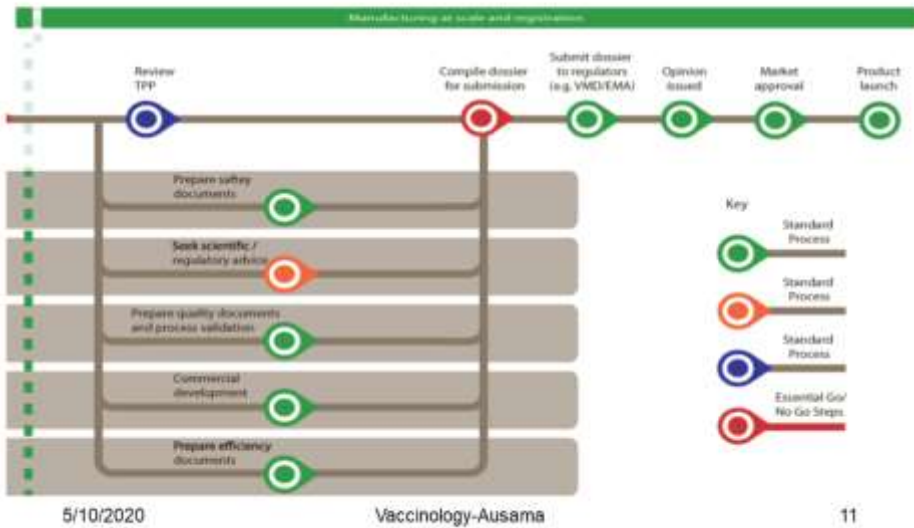
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Vaccine Development Process Map



Veterinary Vaccine: Late-phase Development and Registration 2



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Examples of vaccine development gone wrong



Examples of Development gone wrong



> [Biologicals](#). 2012 Nov;40(6):495-8. doi: 10.1016/j.biologicals.2012.05.001. Epub 2012 Oct 12.

A Case of Mistaken Identity? Vaccinia Virus in a Live Camelpox Vaccine

A A Yousif [†], A M Al-Ali

This example from CU shows how a live vaccine developed for Camelpox turns out to contain vaccinia virus.

Please give suggestions to how this might have happened.