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Experiences from the perspective of a National Regulatory Authority



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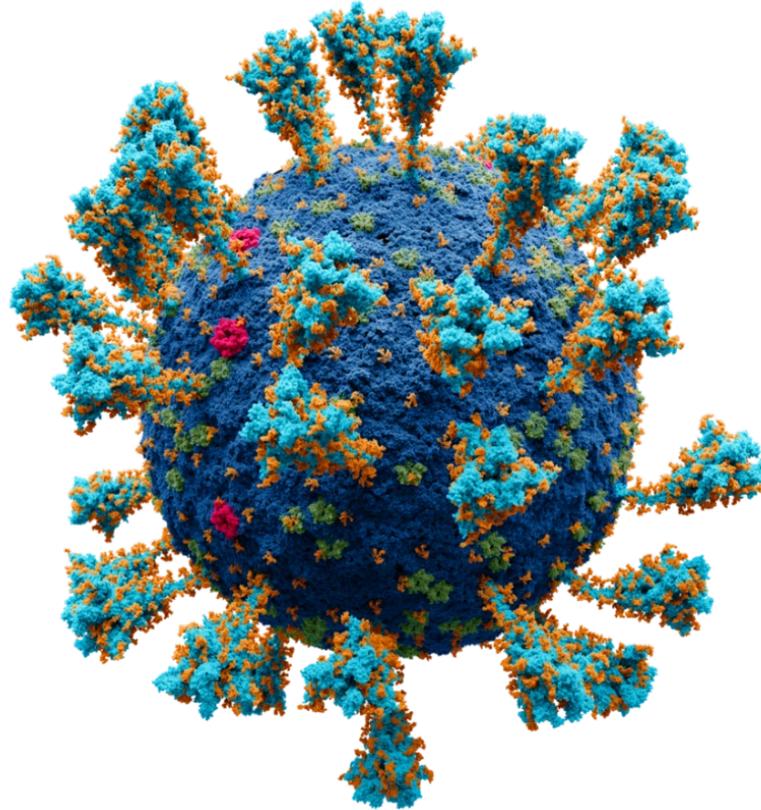
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Determinants of successful regulatory work (and the response to a public health emergency)

- Science
- Regulatory framework
 - GLP, GMP, GCP
- Regulatory flexibility
- Capacity
- Communication
- Motivation

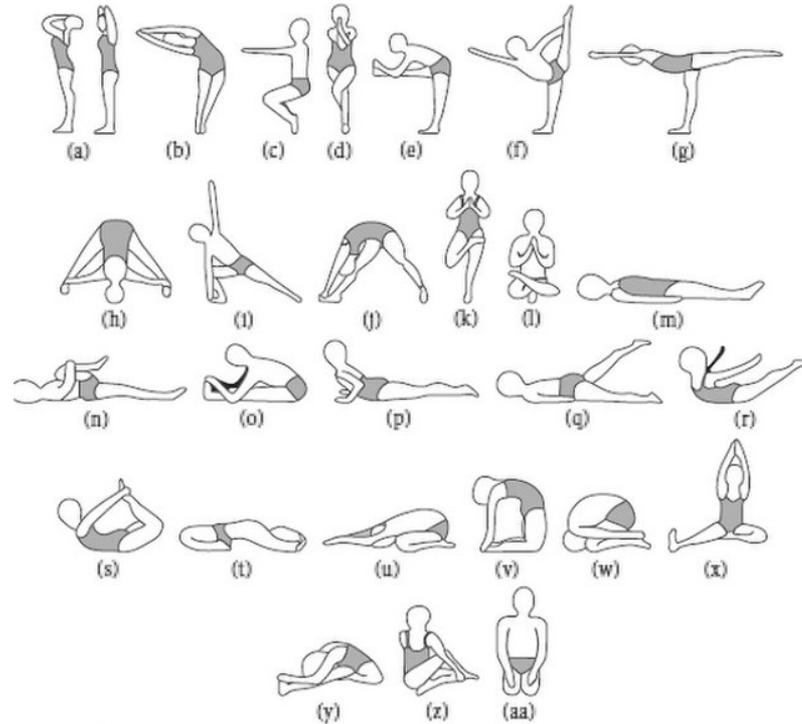
Science



Wikimedia Commons



Regulatory flexibility



Wikimedia Commons: Sequence of asanas

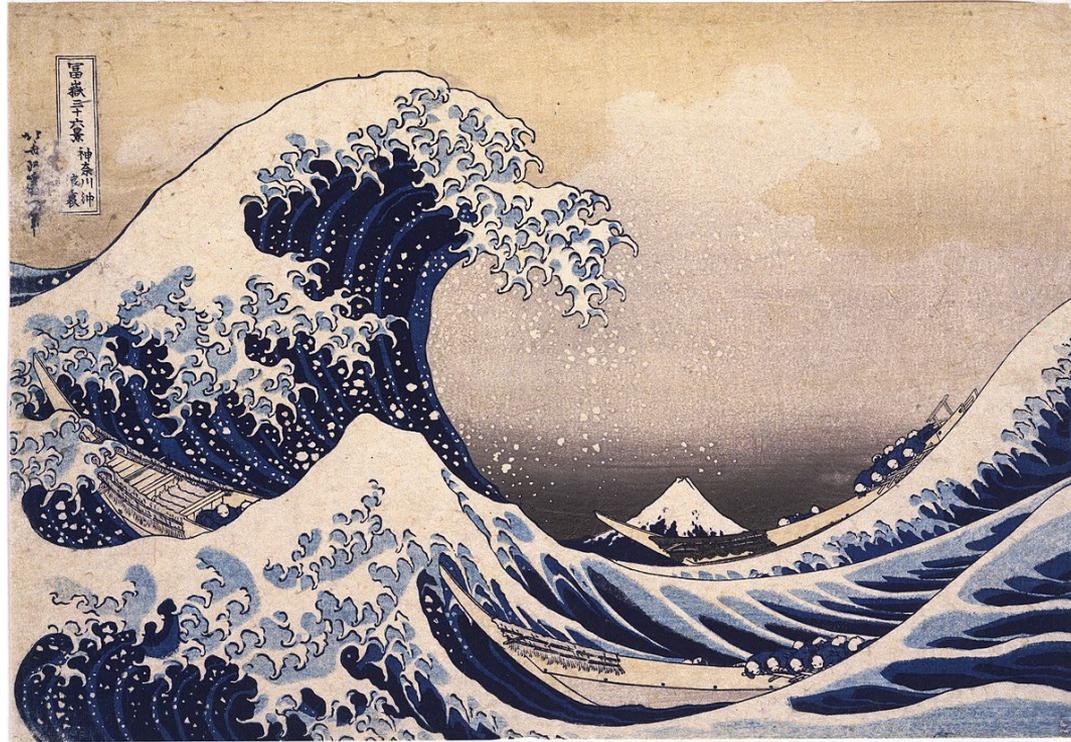


Regulatory flexibility

- Informal exchange prior to formal scientific advice, repeatedly if necessary
- Priorisation, acceleration of COVID-19 related activities
 - Advice
 - Clinical trial authorisation
- Adaptive clinical trials
 - Combination of exploratory and confirmatory phases in one trial
 - Addition of additional cohorts for specific questions
- Extraordinary working party and committee meetings



Rolling review



Wikimedia Commons: Katsushika Hokusai, The great wave off the coast of Kanagawa, 1830

Capacity



- Bundesministerium für Gesundheit provided additional financial support for regulatory responsibilities
 - Personell (new experts for normal duties to free up resources of experienced experts)
 - Establishment of new methods for batch release
- Reassignment of existing personell to pandemic response activities
 - On a limited basis, because normal duties needed to continue as planned



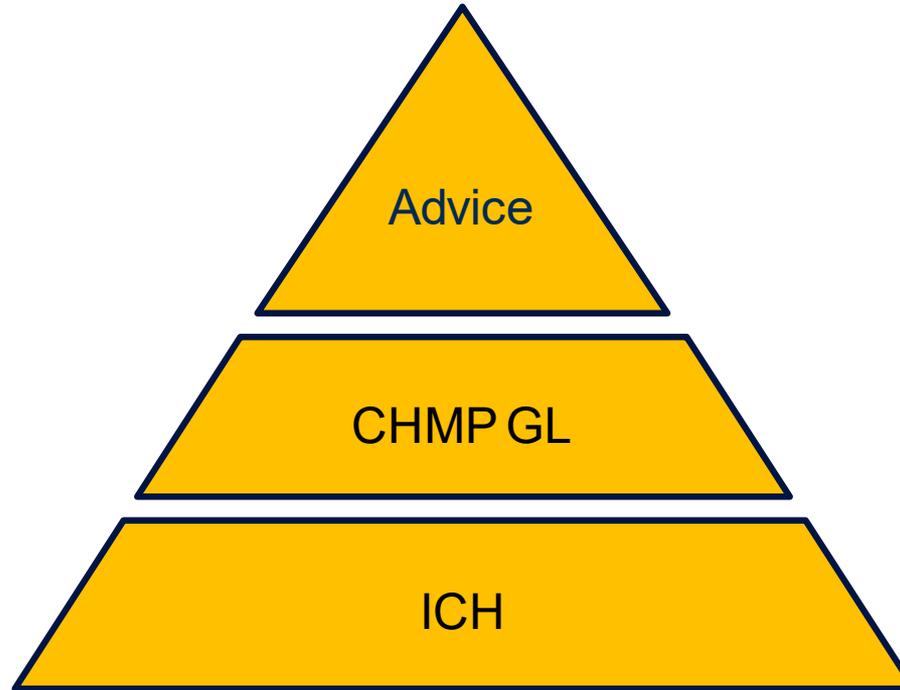
Communication



Wikimedia Commons: Pieter Bruegel the Elder, The Tower of Babel, 1563

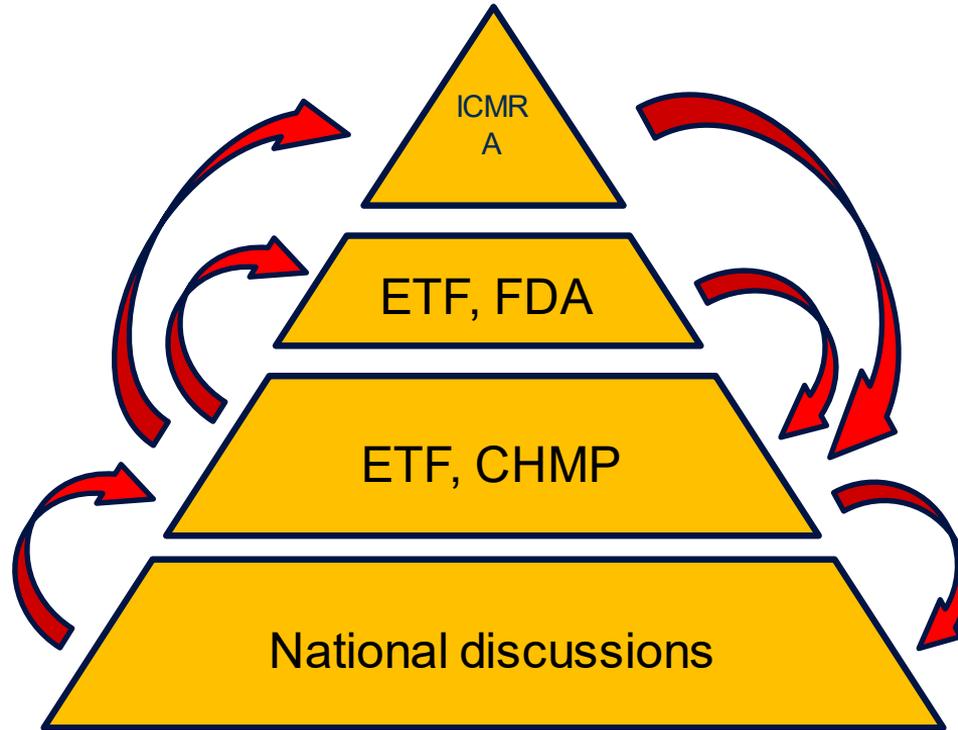


Regulatory guidance





Informal „communications“





Motivated and dedicated teams

- Intrinsic factors
 - Experienced experts
 - High intrinsic motivation
- Extrinsic factor
 - Virtual working environment, IT support
 - Support for home office
 - Requirement for home office likely to have freed-up additional individual resource

THANK YOU!!!



Summary

- Mastering the challenges of the pandemic was possible and highly successful in the current regulatory environment
- A combination of a multitude of factors is necessary to achieve this, but the likely limiting factor is the human resource, i.e. number of qualified experts available



- Questions?

