



Influencing research integrity

Clive Green

Executive Director and AstraZeneca Bioethics Advisory Group
Chair, Discovery Science, BioPharmaceuticals R&D

National Academies, Sponsor Influences on the Quality and
Independence of Health Research: A Workshop

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A composite image with a warm, reddish-orange tint. In the foreground, a woman with curly hair looks thoughtfully to the side. In the background, there are three smaller scenes: medical professionals in scrubs, a parent holding a child, and a glowing molecular structure. The overall theme is healthcare and research.

Research integrity at AstraZeneca

- We address research integrity through our focus on Bioethics – the practical application of ethics to a range of issues that arise from the study and practice of biological and medical science
- Bioethics is a component of Ethics and Transparency, where we aim to build trust by demonstrating integrity, transparency and fair treatment in everything that we do
- Ethics and Transparency is one of the three pillars of Sustainability, alongside Access to Healthcare and Environmental Protection



Bioethics in practise

- We have a Global Bioethics Standard, which covers:
 - Clinical Research and Patient Safety
 - Privacy of Information
 - Data and Artificial Intelligence
 - Human Biological Samples
 - Use of Genomic Information
 - Genome Editing
 - Genetically Modified Organisms
 - Animals in Research and Development
 - Nagoya Protocol
- Sponsor influence in research spans clinical and drug discovery activities



Clinical research integrity

- We maintain a portfolio of research and development projects designed to deliver medicines that are effective, safe, differentiated and address unmet patient needs
- We conduct clinical studies in accordance with all regulatory requirements and the recognized international quality and safety standards in all countries in which we operate
- We make information publicly available about the registration and results of our clinical trials for all products in all phases
- We give those who participate in our clinical studies full, truthful and understandable information and ask for their consent to be part of the study
- We conduct preclinical studies to ensure that all safety aspects have been evaluated and that the assessment of potential risk/benefit justifies the testing of the candidate drug in the clinical setting



Transparency to our actions

We share our approach on our external website

- We share Bioethics content through our Company Sustainability Report and participate in annual external audits
- We register our clinical and observational studies, post study results on disclosure websites, and make a good faith effort to publish our results in peer-reviewed journals, all in a timely way to demonstrate transparency

We provide transparency to Bioethics actions in accordance with applicable legislation, regulations, standards and guidelines





Ensuring compliance with our Standard

- Bioethics responsibilities underpin our Science Policy – one of 4 pillars of our Code of Ethics, which defines our values and behaviours at work
- All employees participate in mandatory, annual training on our Code of Ethics
- Employees also participate in mandatory training on relevant governance policies and procedures specific to their job role
- Concerns about behaviour or activities can be reported to a manager, Human Resources, Legal Department, or Compliance representative; or to an independent third party group acting on AstraZeneca's behalf



Bioethics Advisory Group

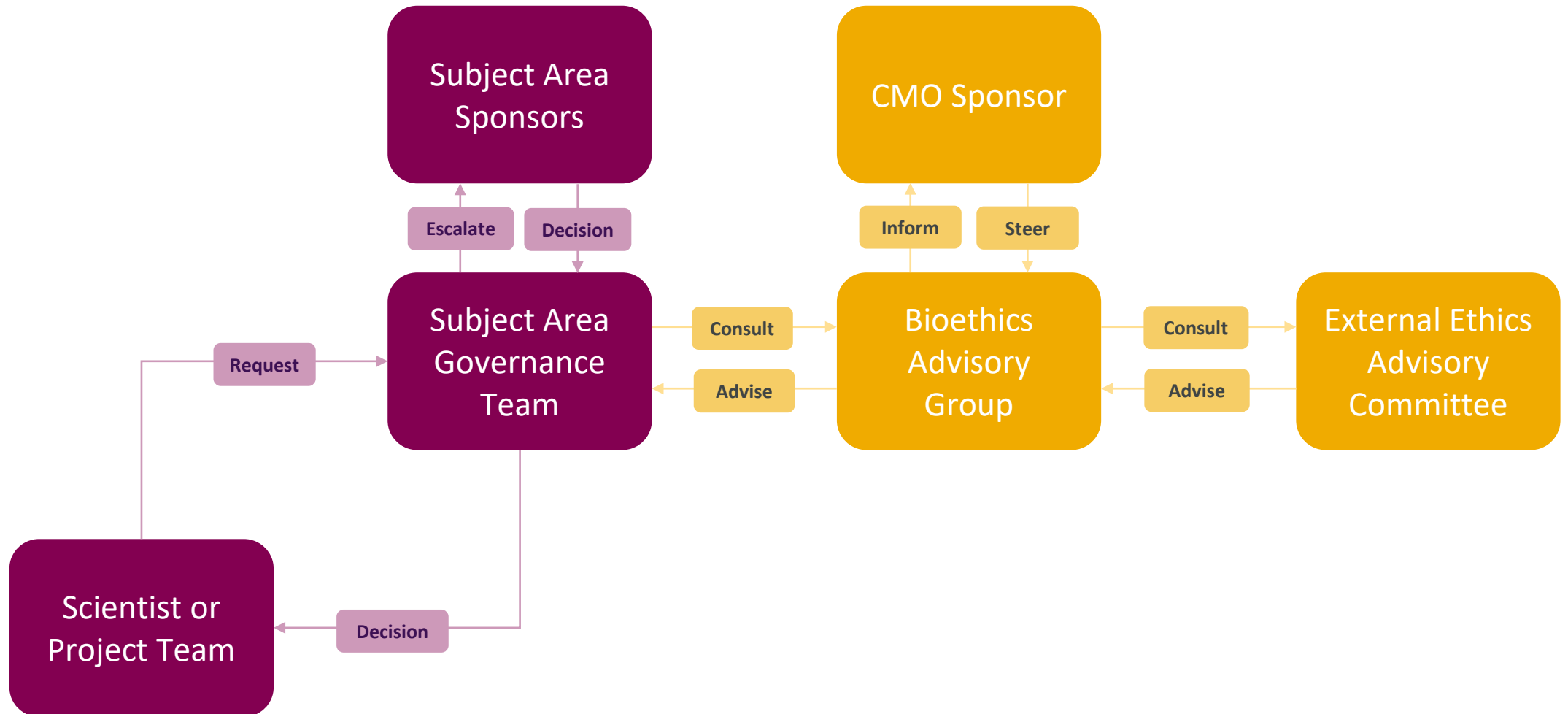
- The Bioethics Advisory Group, sponsored by the Chief Medical Officer, advises the Company on implementation of the Global Bioethics Standard
- Comprises subject experts and business function leaders
- Key activities include:
 - Providing advice, support, and guidance to scientists, project teams and leaders on bioethical issues
 - Maintaining the Global Bioethics Standard and subject-specific Standards
 - Horizon scanning to see where scientific, technical and societal developments will prompt ethical challenges



External Advisory Committee

- Comprises leaders from academic and non-profit institutions
- Provides access to expertise in pharmaceutical, research and public health ethics and law
- The committee serves as a sounding board for proposals, and gives advice and recommendations on ethical issues and societal perspectives
- The committee functions in an advisory capacity, with the advice internalised to AstraZeneca governance and policy groups for decisions

Governance and Advisory Process



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