Simplifying Nagoya for Scientists

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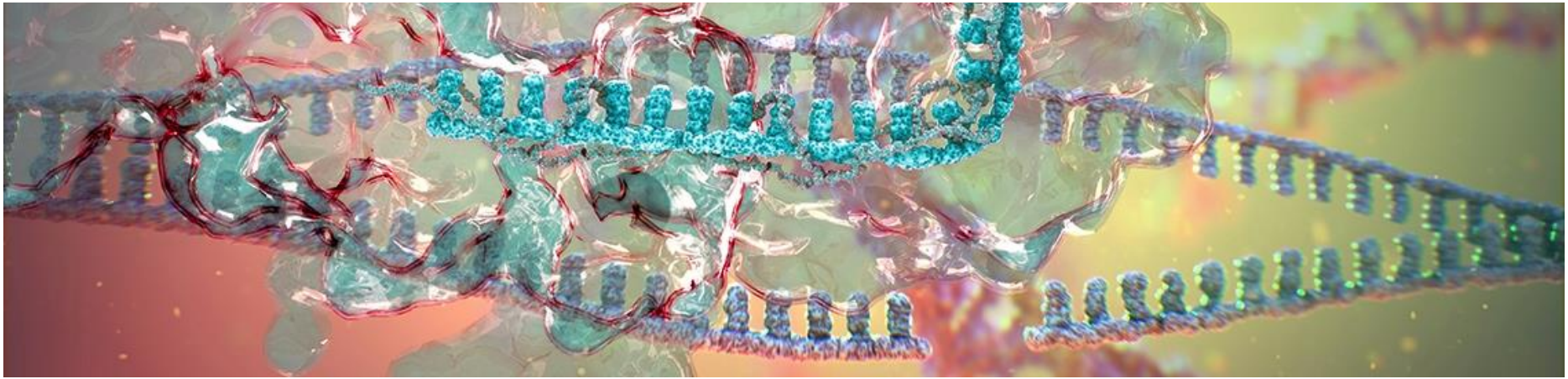
Intellectual Property Awareness Network 7 March 2019



AstraZeneca

We are a global, science-led biopharmaceutical business

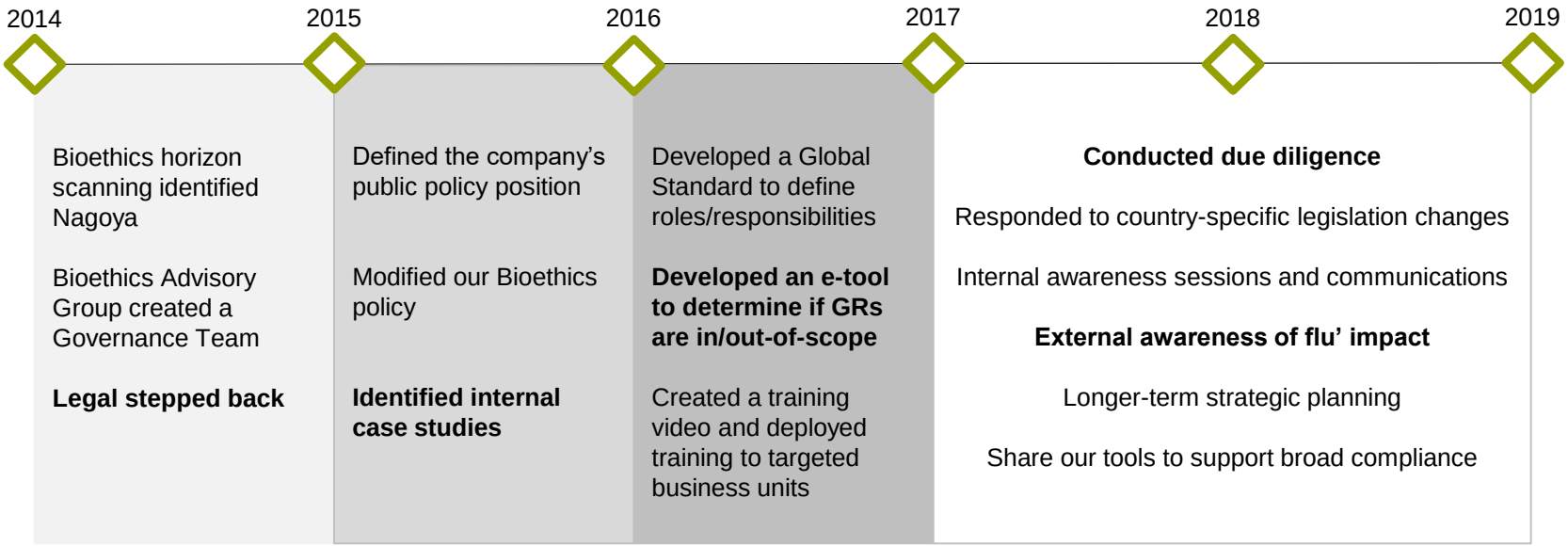
Our R&D relies on new and emerging technologies, is complex and global

Responsible research

Society depends on us to conduct effective, ethical and thorough research in the development of our medicines and treatments. We set high standards of ethical practice across all aspects of our research activity worldwide, from clinical trials to research with animals.

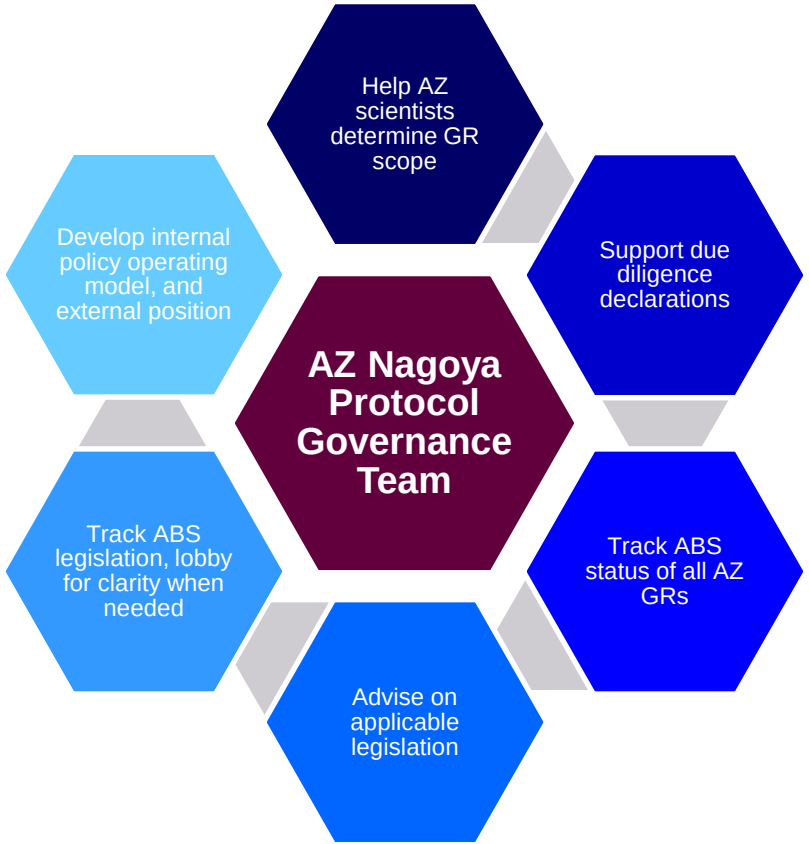
We take every safety precaution and responsible decision required of us by regulators around the world. Our Code of Conduct requires that our research be conducted in accordance with all relevant external laws and regulations. It also requires compliance with our Bioethics Policy, which describes our commitment beyond legal compliance and defines the ethical standards, principles and behaviours governing all our research and development (R&D) activity worldwide. Our Global Standard Expectations of Third Parties document outlines our ethical standards for external partners.

Charting the progress of our Nagoya implementation



We acknowledge the UK Government for sharing their ABS expertise and insight with us

Operating model



Business Representation

- Small molecule R&D
- Antibody R&D
- Regulatory
- Procurement
- SHE
- Sustainability

Access to Legal as needed

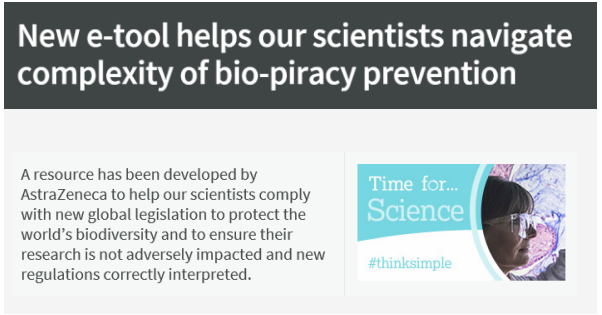
Our Nagoya Protocol toolkit

Standard
- Responsibilities
- Processes
- Actions

Awareness Video
- Overview & context
- Simplify the issue
- What to do when

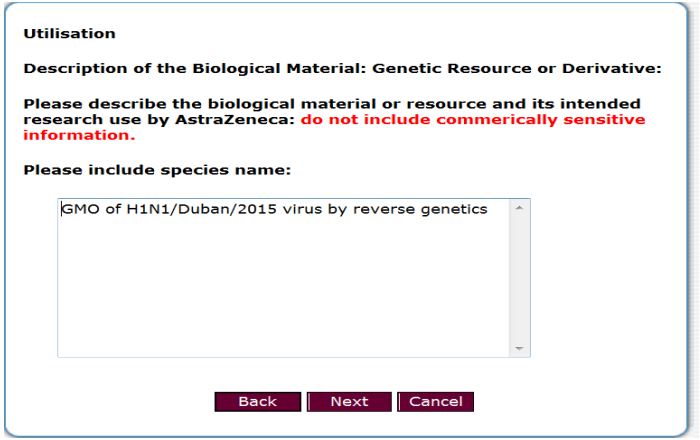
Due Diligence Tool
- For scientists
- Checks in or out of scope
- What to do next
- Documents due diligence

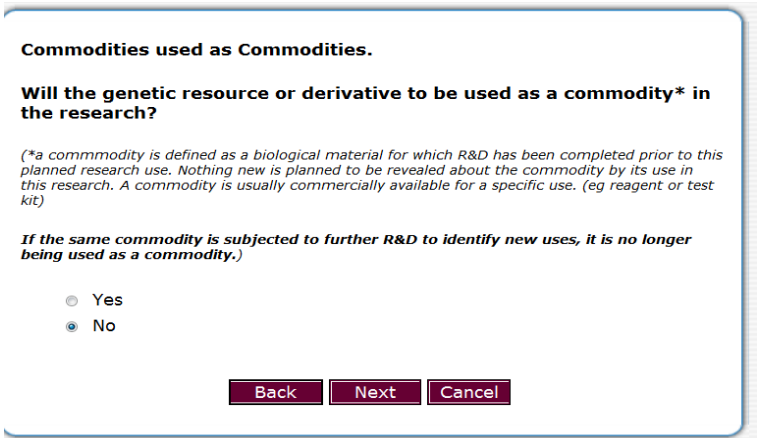
Training Module
- Part of corporate training platform
- Confirms understanding
- Creates a training record

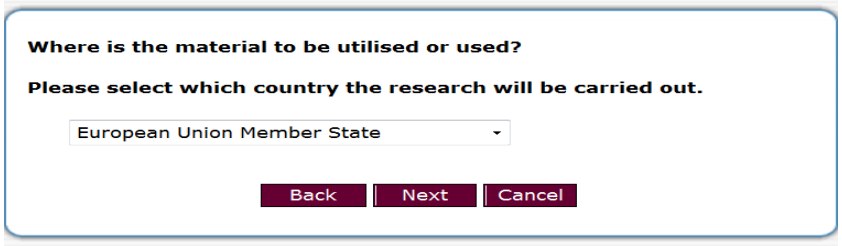


e-Tool for due diligence assessment

Questions include: The material, its use, exceptions, and R&D location







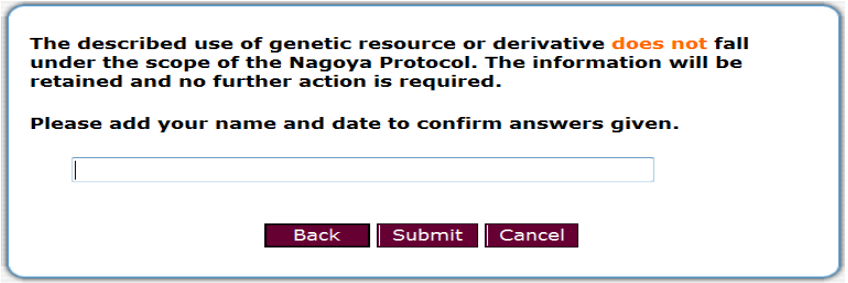
Scope of our R&D activities

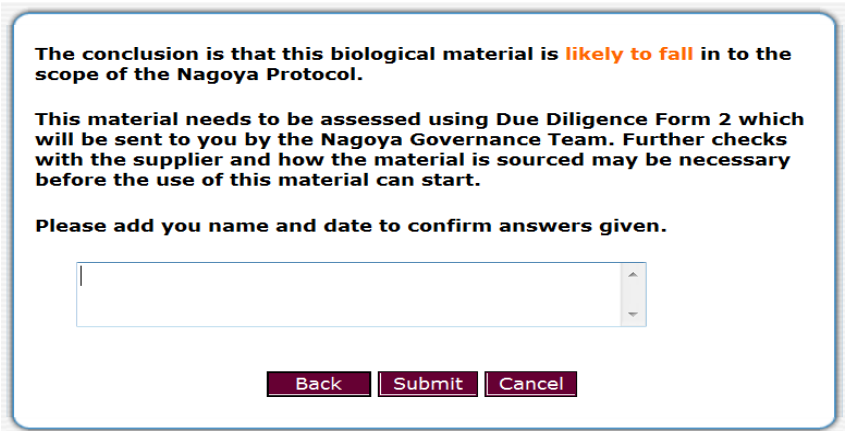
Conducted 15 due diligence investigations spanning >70 materials

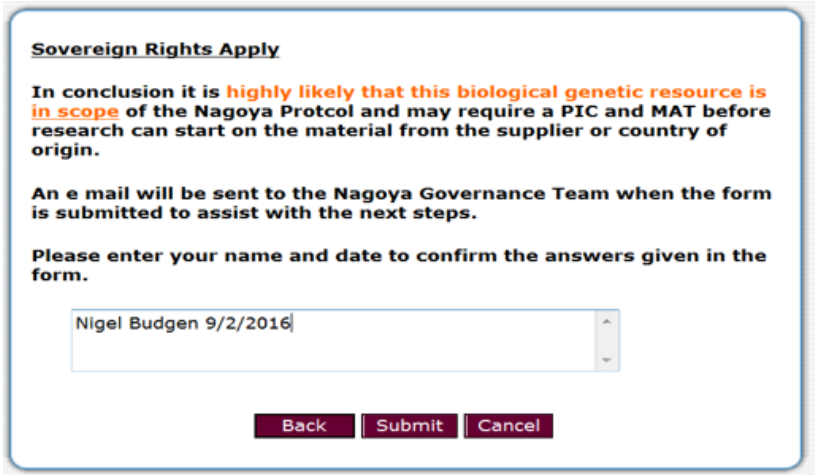
OUT		Animal models used for preclinical & clinical testing
OUT		Commodities used as commodities e.g. excipients
IN		New product developed through R&D on a GR
IN		Chemical leads identified from a GR collection
IN		GR which constitutes the basis of a product e.g. vaccine
IN		GR used in the synthesis of a product

e-Tool for due diligence assessment

Outcomes: Use in or out of scope, more information needed, or PIC/MAT required



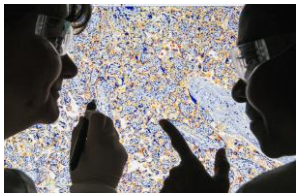




Case Study: Venoms

Scientific hypothesis

- Venom extracts could provide novel chemical start points for projects



Scientific Collaboration

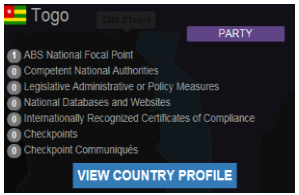
- Opportunistic access to new natural product collections

Due Diligence

- Applied e-Tool
- UK distributor
- 5 African, 4 Asian and US countries
- Pre and post October 2014

Conclusion – STOP R&D

- Countries not parties, or
- Extracted pre October 2014
- No ABS legislation in Togo



What have we learnt?

Developing a compliance framework

- Engage Legal colleagues as part of a business-led effort
- Build experience from your use cases
- Engage Government experts

Executing compliance responsibilities

- Maintain an internal group of subject matter experts
- Assume suppliers know less than you and supply chains will be complex
- Legislation changes; revisit due diligence decisions

Maintaining compliance

- Actively engage with the external community
- Landscape will only get more complex e.g. viruses and DSI
- Limited opportunities to share knowledge

To him that will, ways are not wanting

Confidentiality Notice