

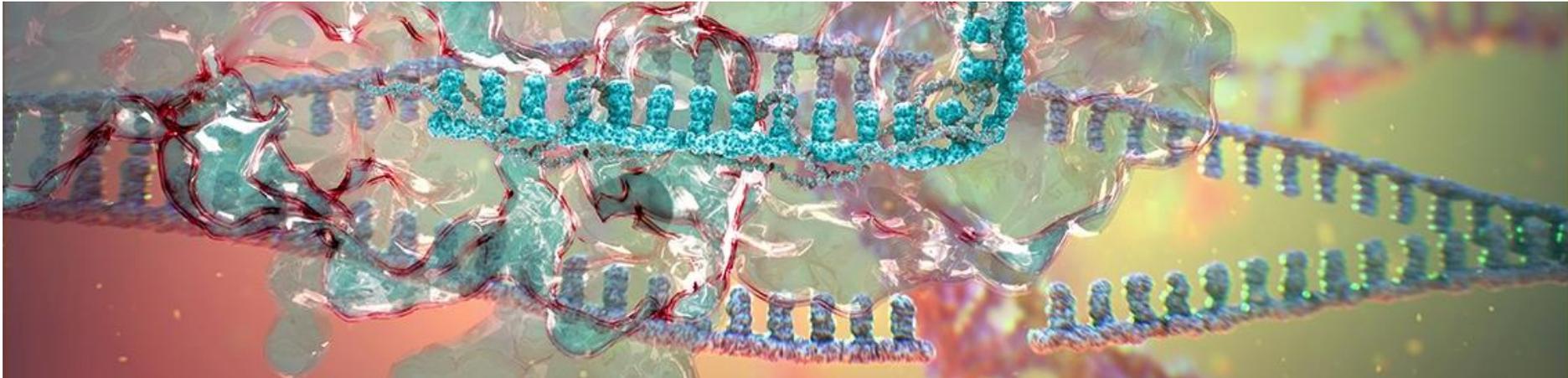
# Simplifying Nagoya for Scientists

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Intellectual Property Awareness Network

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# AstraZeneca

We are a global, science-led biopharmaceutical business



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



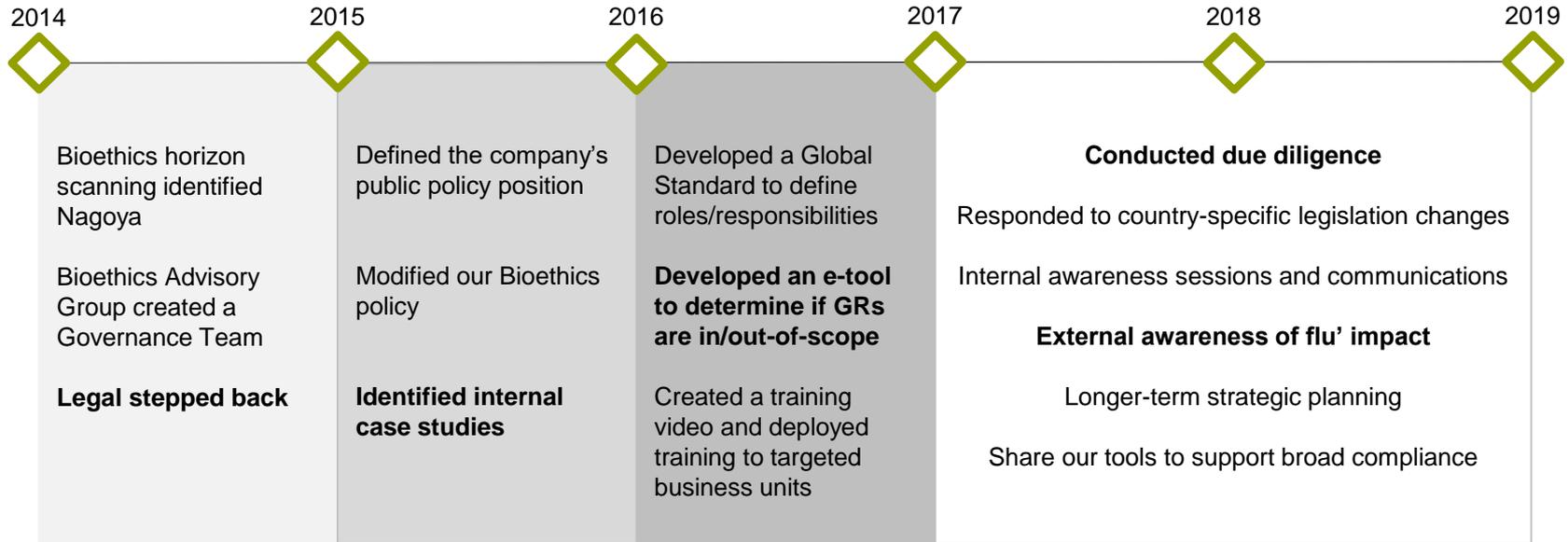


# *Responsible research*

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



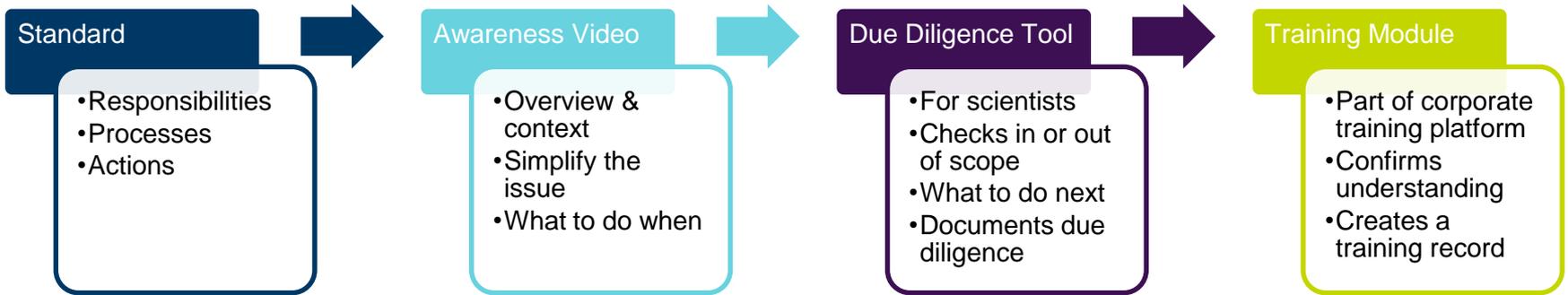
## Business Representation

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

Access to Legal as needed



# Our Nagoya Protocol toolkit



## New e-tool helps our scientists navigate complexity of bio-piracy prevention

A resource has been developed by AstraZeneca to help our scientists comply with new global legislation to protect the world's biodiversity and to ensure their research is not adversely impacted and new regulations correctly interpreted.



# e-Tool for due diligence assessment

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

**Utilisation**

**Description of the Biological Material: Genetic Resource or Derivative:**

**Please describe the biological material or resource and its intended research use by AstraZeneca: do not include commercially sensitive information.**

**Please include species name:**

GMO of H1N1/Duban/2015 virus by reverse genetics

**Commodities used as Commodities.**

**Will the genetic resource or derivative to be used as a commodity\* in the research?**

*(\*a commodity is defined as a biological material for which R&D has been completed prior to this planned research use. Nothing new is planned to be revealed about the commodity by its use in this research. A commodity is usually commercially available for a specific use. (eg reagent or test kit)*

*If the same commodity is subjected to further R&D to identify new uses, it is no longer being used as a commodity.)*

Yes

No

**Where is the material to be utilised or used?**

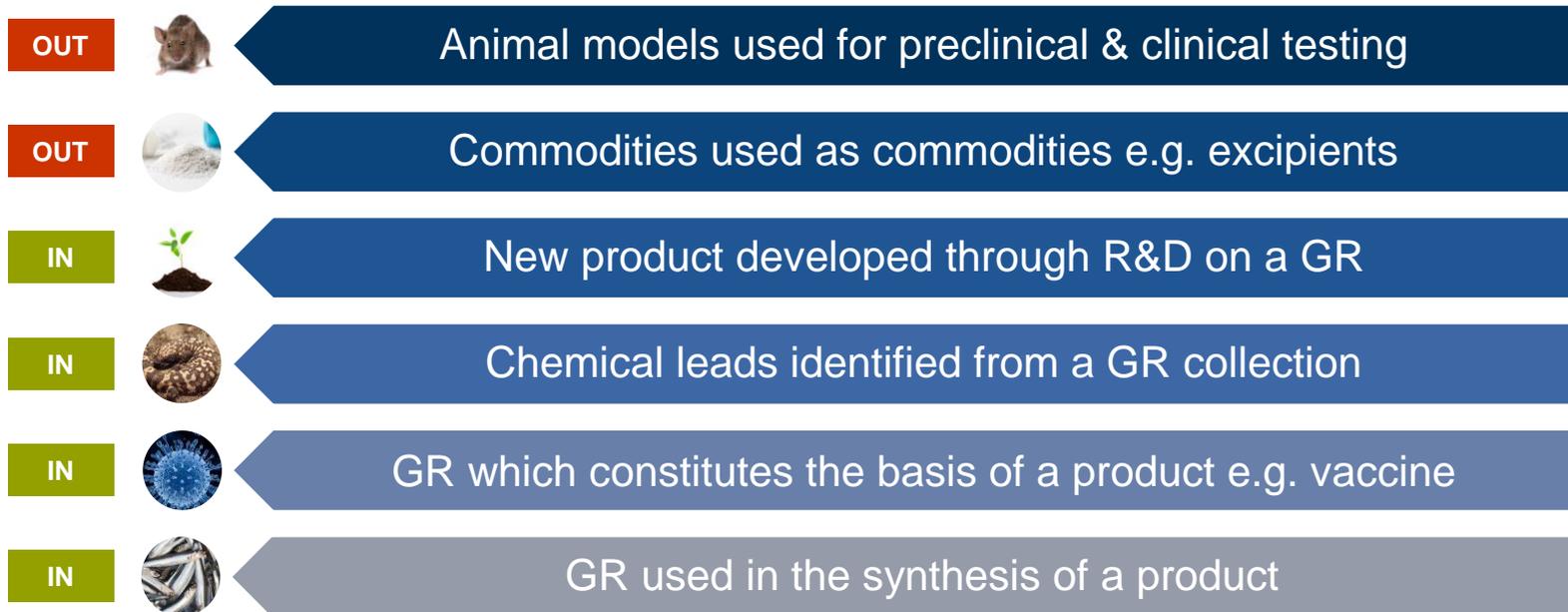
**Please select which country the research will be carried out.**

European Union Member State



# Scope of our R&D activities

Conducted 15 due diligence investigations spanning >70 materials



# e-Tool for due diligence assessment

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

The described use of genetic resource or derivative **does not fall** under the scope of the Nagoya Protocol. The information will be retained and no further action is required.

Please add your name and date to confirm answers given.

Back

Submit

Cancel

The conclusion is that this biological material is **likely to fall** in to the scope of the Nagoya Protocol.

This material needs to be assessed using Due Diligence Form 2 which will be sent to you by the Nagoya Governance Team. Further checks with the supplier and how the material is sourced may be necessary before the use of this material can start.

Please add you name and date to confirm answers given.

Back

Submit

Cancel

## Sovereign Rights Apply

In conclusion it is **highly likely that this biological genetic resource is in scope** of the Nagoya Protocol and may require a PIC and MAT before research can start on the material from the supplier or country of origin.

An e mail will be sent to the Nagoya Governance Team when the form is submitted to assist with the next steps.

Please enter your name and date to confirm the answers given in the form.

Nigel Budgen 9/2/2016

Back

Submit

Cancel



# 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**



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