Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Regulatory considerations for early clinical development

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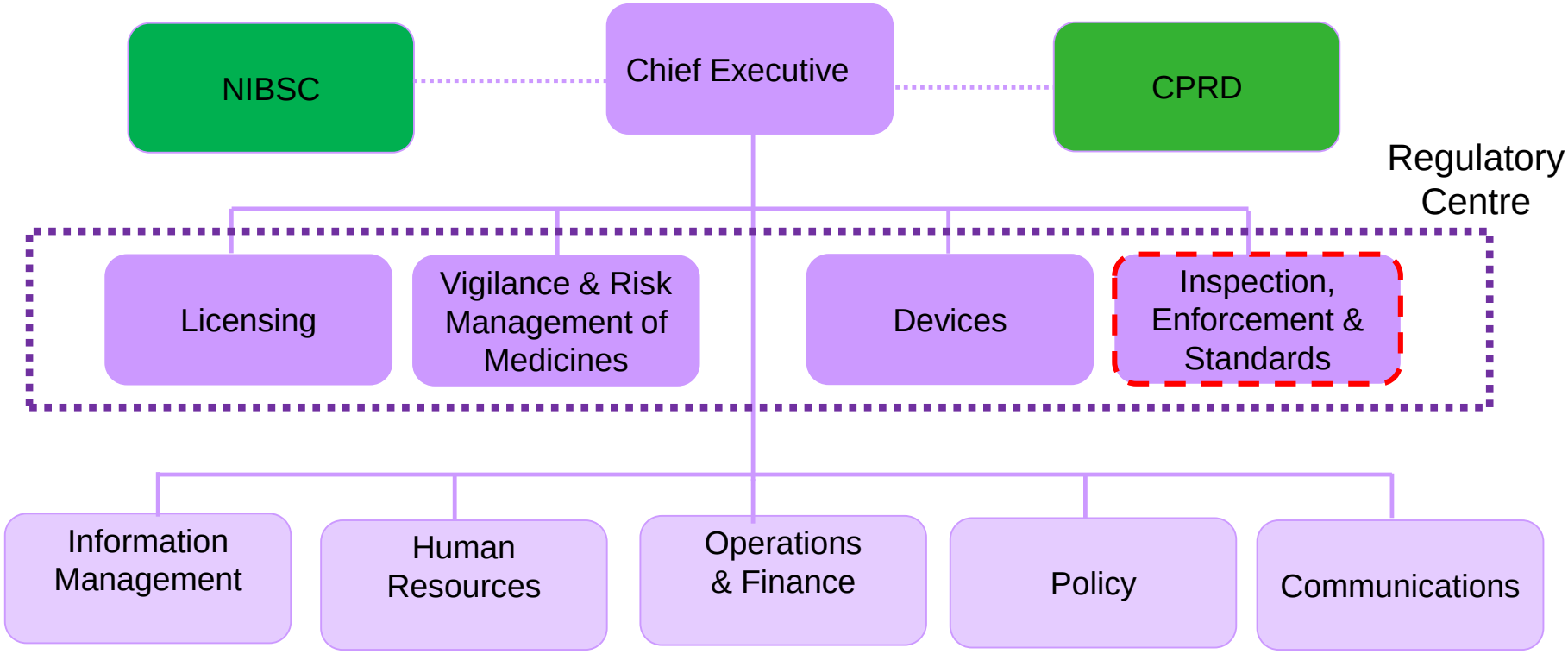
MHRA

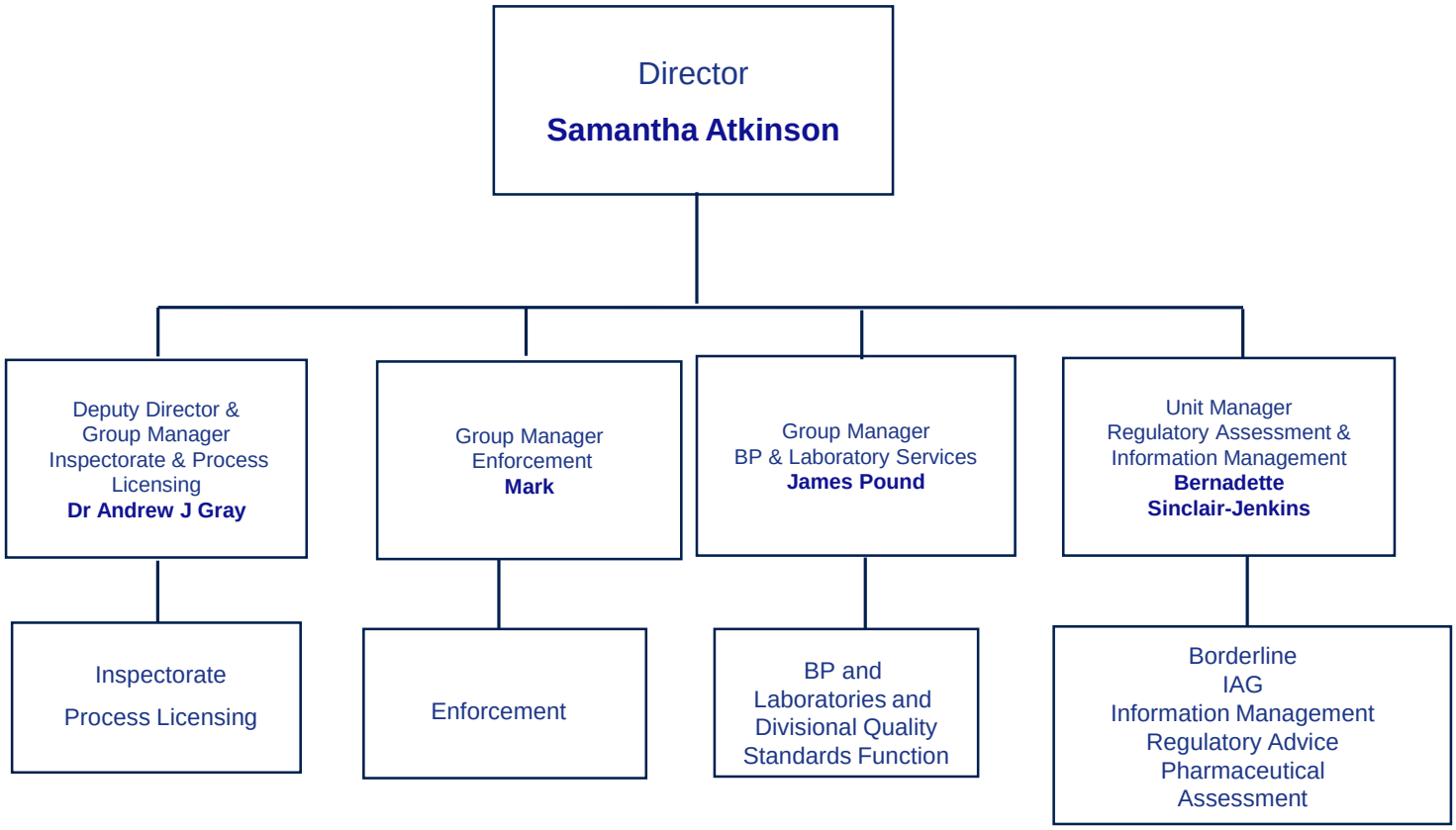
We protect and improve the health of millions of people every day through the effective regulation of medicines, medical devices and blood, underpinned by science and research

MHRA structure



- Government trading fund and an executive agency of DHSC
- Approx 1350 staff
- Head office - 10 South Colonnade, Canary Wharf
- NIBSC - South Mimms, Hertfordshire
- BP and MHRA laboratories based at LGC in Teddington

MHRA structure – Inspection Enforcement and Standards



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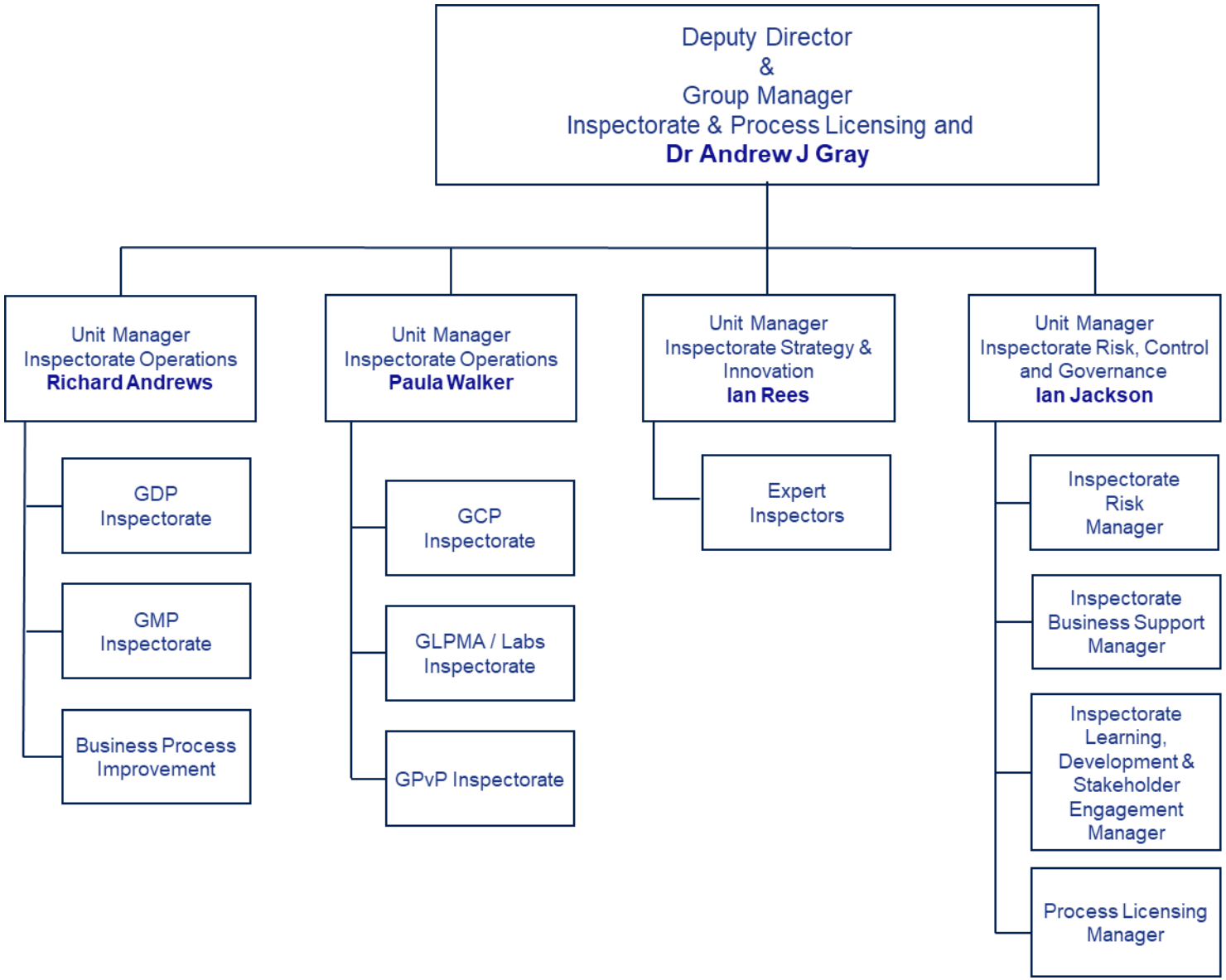


UK exit from the EU

Background

- UK’s exit - extended to 31 October 2019
- Full participation in the EU regulatory network until exit
  - Close future regulatory partnership desired
- Focus remains on negotiating a withdrawal agreement
  - Implementation period (with no regulatory change) until end 2020
- Responsibility to prepare for all scenarios, including ‘no deal’
  - New legislation – EU (Withdrawal) Act, changes only where required to address changes / new risks
  - Detailed technical guidance
  - Information exchange: new submissions and publishing portal for UK.

Central point for ‘no deal’ EU exit information

https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario

Authorisations and certificates

- Clinical Trials
  - Continued participation in multinational trials
- Marketing Authorisations
  - UK legal presence for MAH
  - Grandfathering CAPs
  - New assessment procedures (targeted, accelerated, rolling)
  - Packaging

UK Supply chain

- Maintaining patient access
- Recognition of existing partners QC, QP and inspection arrangements
- ‘Listed countries’
- Importation into the UK
  - Authorised products
    - Wholesaler importation from listed countries
    - ‘Responsible Person (import)’
  - Investigational Medicinal Products
    - Direct to UK CT site
    - Supply chain oversight by UK QP
- Written Confirmation for API exports from UK to EEA.

Inspections

- Risk based programme
- UK and third country
- Continued integration into PIC/S and ICMRA work sharing initiatives
- GMP certificates for UK & EU MA submissions.

International network

- Close future alignment with EU regulatory system
- Continued participation in the PIC/S network
- Mutual recognition agreements and bilateral working
- Continued participation in international harmonisation initiatives
  - ICH, ICMRA
- Council of Europe conventions unaffected
  - Pharmacopoeia, EDQM.

Support for innovation

Product lifecycle – support

Discovery

Preclinical

Clinical trials

Marketing authorisation

Widespread adoption

Inspections and assessments

International – EU PIC/S ICH ICMRA bilaterals

Innovation Office One Stop Shop

Scientific Advice

EAMS

NIHR/NOCRI

NICE

Research Councils

Innovate UK

Catapults

Accelerated Access Collaborative

MHRA Corporate Plan 2018-23

1. We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products including through enhanced partnerships in the UK and internationally
2. We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences
3. We will deliver robust proactive integrated vigilance for medicines and healthcare products and improve the way we share information to achieve measurable public health benefit
4. We will ensure the safe production and supply of medicines and healthcare products through enhanced systems and strong international partnerships
5. We will be an exemplar of organisational excellence and efficiency

MHRA Innovation office

Aim – to make innovation operational: clarify and de-risk new projects and processes

Launched 2013, ~770 enquiries and >130 regulatory meetings

Free and confidential regulatory advice to all organisations - academia, hospitals, industry, consortia

Advice at any stage of development ⇨ **the earlier the better**

Lead to:

- Further meetings, depending on complexity of the project
- Scientific advice meetings, interim inspections etc

Regulatory Advice Service for Regenerative Medicine

Also known as the ‘One Stop Shop’ – provides access to all UK regulators

Launched in 2014 and received ~90 enquiries to-date

Objectives as for IO – geared for regenerative medicines

MHRA Regulating Medicines and Medical Devices

HTA Human Tissue Authority

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

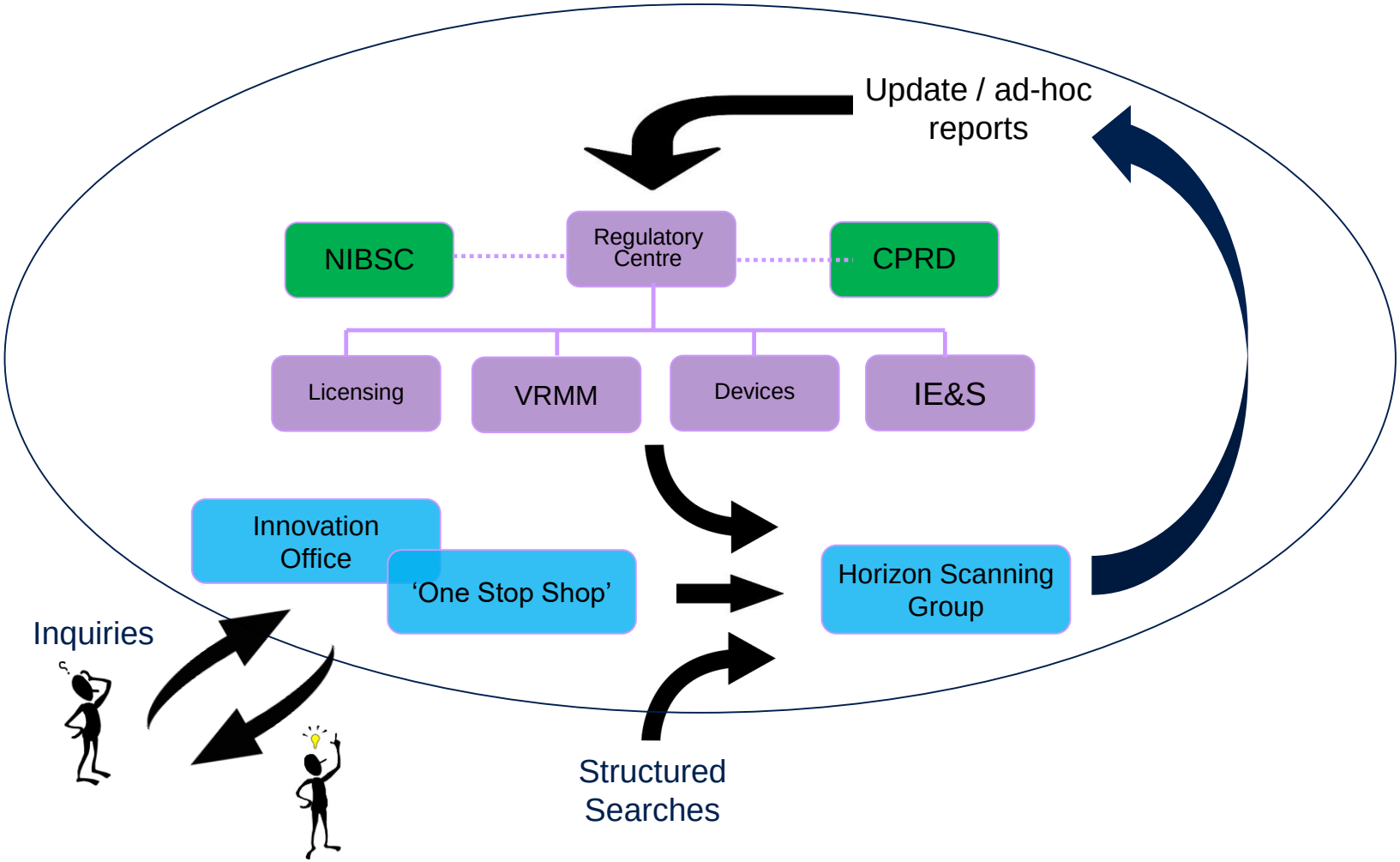
NHS Health Research Authority

defra Department for Environment Food and Rural Affairs

NICE National Institute for Health and Care Excellence

HSE Health & Safety Executive

Linking IO/OSS and the Horizon Scanning Working Group



IO/OSS next step - scientific advice

Formal, fee-bearing meeting

Product-specific

- For one medicinal product or drug-device combination only

Broader scope

- Not product-specific, e.g. new trial study design in a disease area, a new manufacturing process to be used across a range of products

MHRA-NICE joint scientific advice

- Joint meeting with both agencies and advice given in parallel

Sources of advice from MHRA Clinical Trials Unit

Scientific / Regulatory advice

- 75-100 meetings per year.
- Exceptionally – “house calls” to discuss proposed studies (e.g. visiting hospital running 3 cell therapy trials)

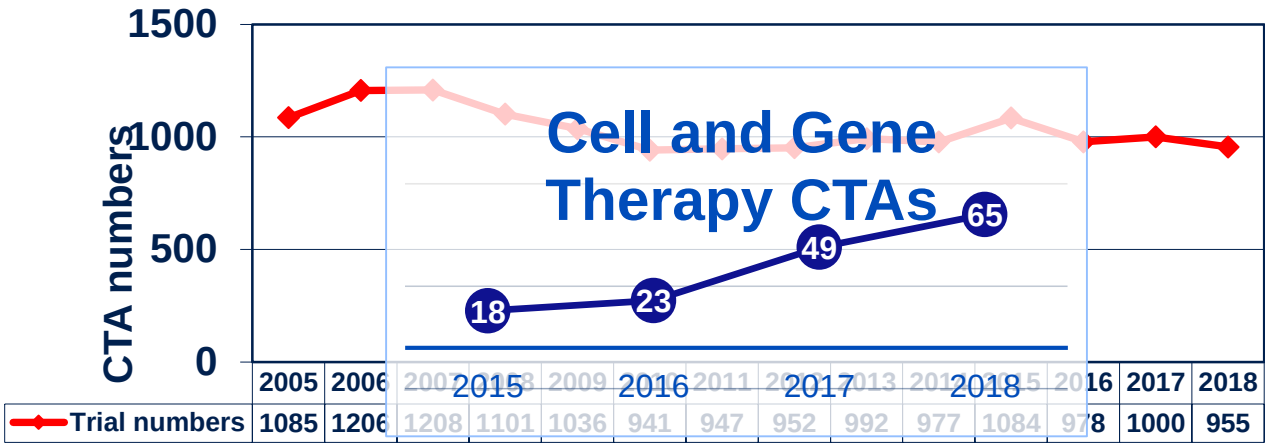
Dedicated Clinical Trial Helpline

- Clintrialhelpline@mhra.gov.uk
- Approx. 3500 emails + 5000 phone calls per year
- 14 day target response (currently ~4 days)

Access to assessors

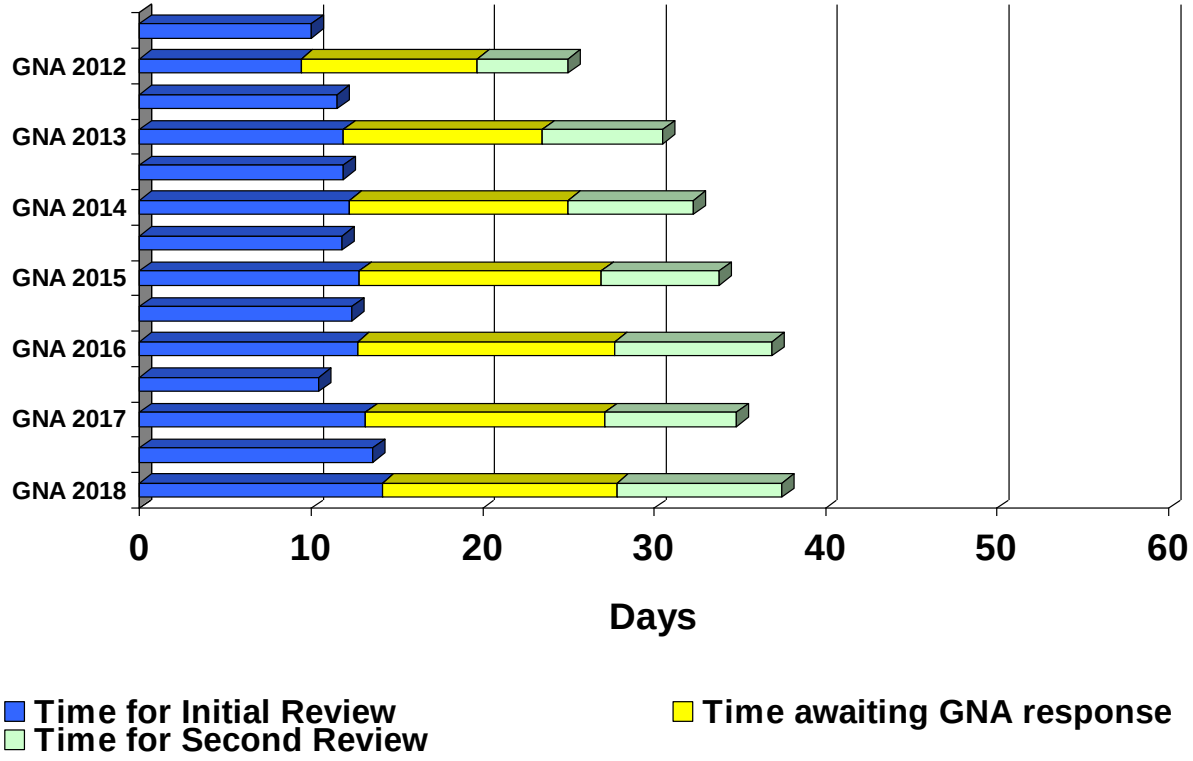
- Direct phone number/email address provided in request for information letters

General UK clinical trials environment



- Total numbers relatively stable
- First in Human trials increased from 69 in 2016 to 105 in 2017
- 37% increase in UK cell and gene therapy trials (2017-2018) (Cell and Gene Therapy Catapult)

Timelines: CT Assessment - Phase 1 Performance



Summary - MHRA support for innovation

Thank you for your attention