HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA supports for clinical research and its involvement in the STARS project

Enabling Ireland as a Clinical Research Leader Conference
Dr Caitriona Fisher, Director of Scientific Affairs, HPRA

13 May 2019

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA national supports

HPRA's regulatory role

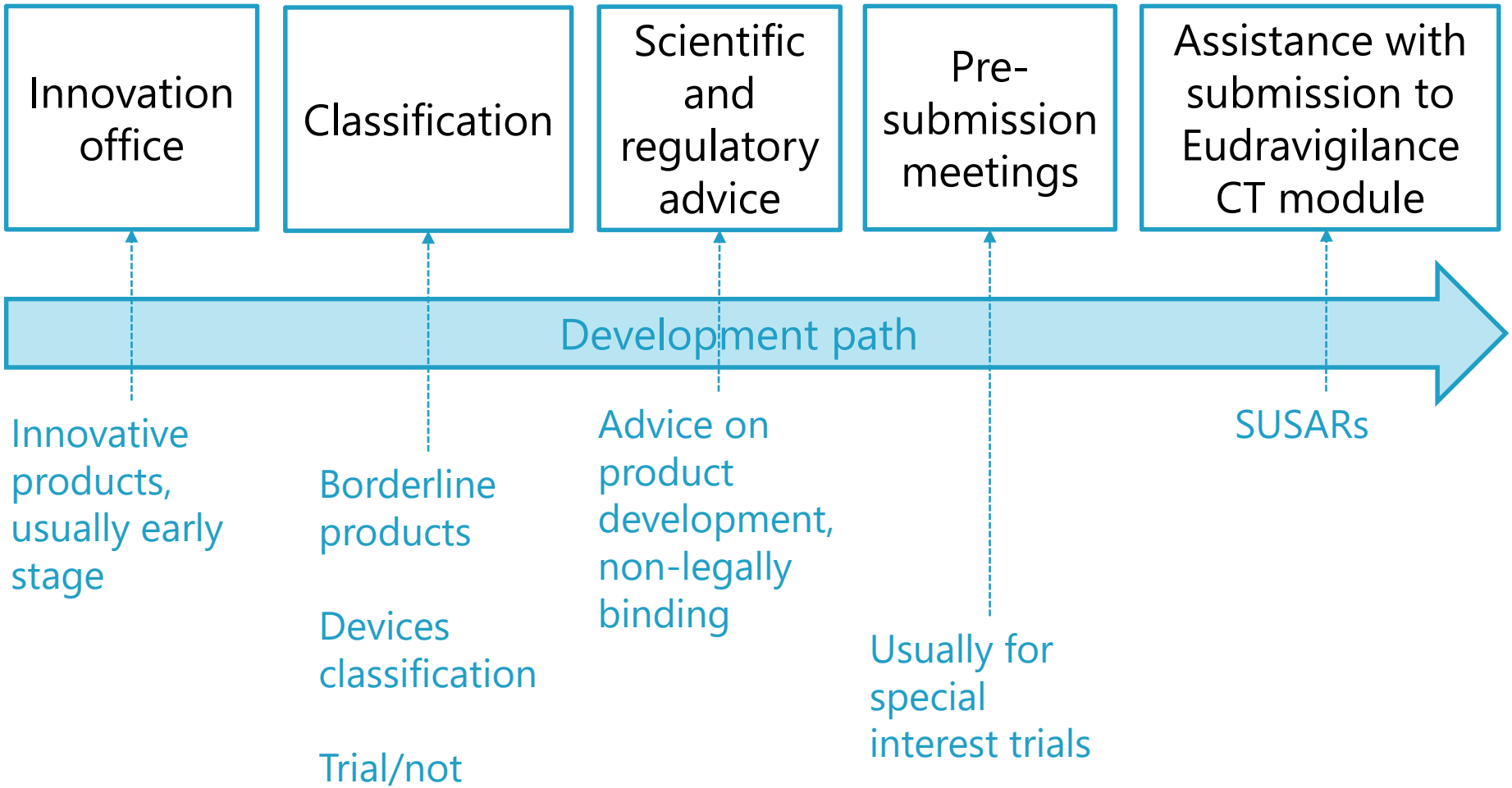
Medicines

- Authorise clinical trials and amendments
- Review safety data
- Conduct GCP inspections to verify compliance

Medical devices

- Authorise clinical investigations and amendments
- Review safety data
- Will be carrying out inspections of sites under new Regulations

HPRA supports: application assistance

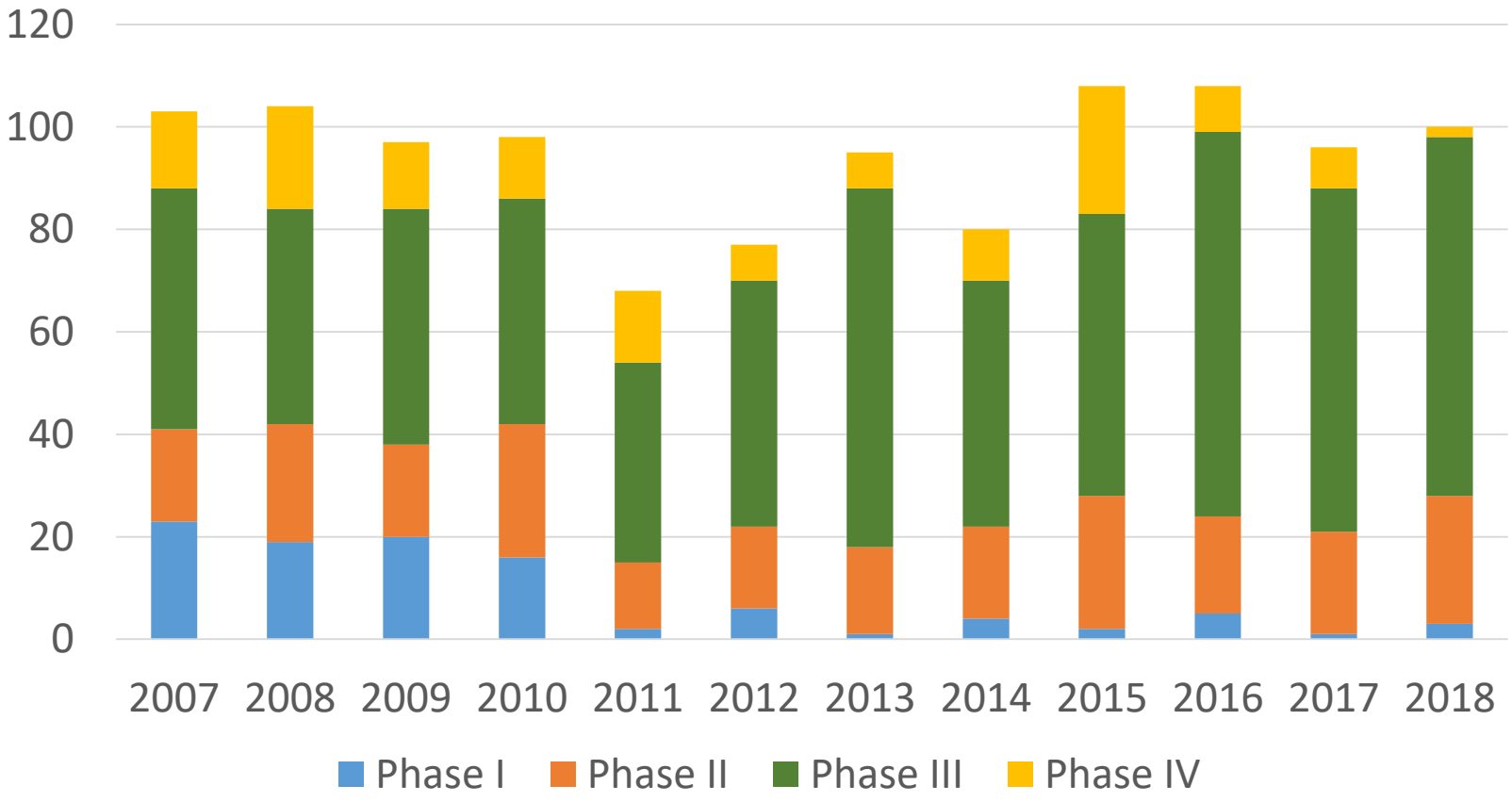


HPRA supports: resources

General:	Information days
E-mail:	innovationoffice@hpra.ie clinicaltrials@hpra.ie (applications) compliance@hpra.ie (inspections) devices@hpra.ie
Website:	hpra.ie/…/clinical-trials - or – clinical investigations
Documents:	Guide to clinical trial applications, protocol template; Guide for manufacturers and sponsors on clinical investigations carried out in Ireland
Fees:	None/reduced for non-commercial sponsors

HPRA approved trials

Medicines



HPRA supports: future oriented

- Clinical Trials Regulation - pilot project in progress
- Medical Devices Regulation

- CRDI Future Resourcing of Clinical Research; training programmes
- CRCI Annual meeting on GCP inspections

- EU Innovation Network of medicines agencies, leading on horizon-scanning
- Led innovation project in 2018-9 among international medicines agencies
- STARS: Horizon 2020 project

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

STARS project

STARS
STRENGTHENING
REGULATORY
SCIENCE

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

CSA STARS
Coordination and Support Action
Strengthening Training of Academia in Regulatory Sciences and supporting regulatory scientific advice

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

Background

- Horizon 2020 coordination and support action
- Scheduled to run from Jan 2019 to Dec 2021
- Project consortium:
  - National competent authorities for medicines from 18 EU MSs
  - European Medicines Agency

  Active involvement of other stakeholders also foreseen
- To facilitate the translation of academic research into authorised medicines and ultimately into clinical practice
- Relates to both new and existing medicines (new indications, new treatment regimens)

Objectives

- To improve the direct regulatory impact of results obtained in clinical research
- To reach academic researchers very early in the planning of relevant grant applications
- To strengthen regulatory knowledge in general by reaching clinical scientists during professional training and qualification

Key Deliverables

Establish and maintain a comprehensive inventory of existing regulatory support activities

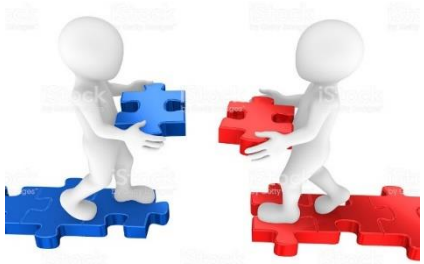
Develop:
a) Core curriculum for the training of clinical scientists
b) Comprehensive curriculum defining relevant regulatory knowledge for post-graduate programmes

Implement three pilot projects:
1) To transfer best practice training programme to other EU countries
2) To implement a novel support activity addressing gaps in regulatory knowledge
3) To implement the comprehensive curriculum

Develop a common strategy to strengthen regulatory knowledge among academic researchers

Next steps and further information

- Nominated research centres, academic researchers and funding bodies will complete questionnaires to confirm the current level of regulatory knowledge and provide feedback in relation to available regulatory support
- European stakeholder workshop planned for mid-2020 and global regulatory science conference scheduled for end 2021
- Regular updates will be published on the STARS website (www.csa-stars.eu) and the HPRA website (www.hpra.ie)



HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Conclusion

HPRA supports for clinical research

We are committed to:

- Engagement and mechanisms to support and enable clinical research
- Improving the standard of GCP compliance by all sponsors and investigators

Ultimately, the goal is optimise patient outcomes by facilitating access to innovative medicines and devices

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thank you