

## PROVIDER PROFILE

<b>Name of the organisation</b>	Health Products Regulatory Authority (HPRA)
<b>Type of the organisation</b>	National Competent Authority
<b>Contact email(s)</b>	<a href="mailto:innovationoffice@hpra.ie">innovationoffice@hpra.ie</a> ; <a href="mailto:scientificadvice@hpra.ie">scientificadvice@hpra.ie</a> ; <a href="mailto:clinicaltrials@hpra.ie">clinicaltrials@hpra.ie</a>
<b>Offering website</b>	<a href="https://www.hpra.ie/homepage/about-us/stakeholders/innovation-office">https://www.hpra.ie/homepage/about-us/stakeholders/innovation-office</a>
<b>Service language(s)</b>	English
<b>Target group</b>	Academic Principal Investigators/Groups/Consortia, SMEs, Big Pharma
<b>Short support description</b>	<p><b>Innovation Office:</b> The HPRA's Innovation Office provides regulatory support and advice to anyone, including academics, developing an innovative health product or technology. Queries can relate to any area regulated by the HPRA including medicines, medical devices, drug-device combination products and cosmetics. The Innovation Office can advise individuals or companies directly on regulatory requirements and provide general guidance on technical or scientific issues that they need to consider during the development of their product or technology.</p> <p><b>Scientific Advice:</b> The HPRA can provide national scientific and regulatory advice to commercial and non-commercial entities. The overarching aim is to assist applicants in the development of new or existing human medicinal products by taking into account the current knowledge of a given condition, targeted patient population, existing treatment modalities and specificities of the product being developed. The advice may assist applicants in the confirmation of guidelines, provide information where guidelines do not exist on regulatory aspects or provide assistance to non-commercial bodies such as academics intending to submit a clinical trial investigation.</p> <p><b>Clinical Trials:</b> Pre-submission meetings can be arranged for academic sponsors intending to submit applications to conduct clinical trials in Ireland. The HPRA's Guide to Clinical Trial Applications which is available on the HPRA website includes specific guidance for non-commercial (academic) sponsors. A protocol template is also available for academic sponsors on request to <a href="mailto:clinicaltrials@hpra.ie">clinicaltrials@hpra.ie</a>.</p>

This profile is part of the [Comprehensive Inventory \(CI\)](#) provided by the [STARS project](#).

Purpose of the CI is to assist European academic drug developers in finding support on regulatory affairs. The inventory lists various support services provided by national competent authorities, public actors and private entities.

For information about the STARS project please visit [www.csa-stars.eu](http://www.csa-stars.eu) or contact [CoordinationSTARS@bfarm.de](mailto:CoordinationSTARS@bfarm.de).