

Update from NRS Reproductive Health and Childbirth Specialty Group

June 2023/ An t-Òg-mhìos 2023

Scotland is a stronghold for the otter (*Lutra lutra*),
regularly seen in Shetland



Independent Report



Department for
Science, Innovation,
& Technology



Department
of Health &
Social Care



Office for
Life Sciences

Commercial clinical trials in the UK:

The Lord O'Shaughnessy Review – final report

This independent review was commissioned by the UK Government to offer recommendations on how commercial clinical trials can help the life sciences sector unlock UK health, growth and investment opportunities.

The review sets out 27 recommendations intended to deliver major, sustained growth in commercial trial activity. Whilst it focuses on the systems and structures in England, many of the recommendations made in the review are applicable to the whole system, across all four nations of the UK. See Full Article [here](#).

Find The Lord O'Shaughnessy Review [here](#) and [UK Government response to the review](#).

Open consultation. Consultation on the International Council for Harmonisation (ICH) E6 (R3) Good Clinical Practice (GCP) Guidelines. Further information [here](#).



The Medicines and Healthcare products Regulatory Agency (MHRA) became a full member of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in May 2022 and is consulting with UK stakeholders on the ICH E6 (R3) Good Clinical Practice (GCP) guidelines to compile feedback to ICH.

This consultation closes on 31 August 2023

RH&C COMMERCIAL STUDIES IN SCOTLAND

Active

- ❖ **DMPA-XT.** A Phase 3, Open-Label, Multicenter Study to Evaluate Contraceptive Efficacy and Safety of Depot Medroxyprogesterone Acetate (150 mg/mL) Injected Subcutaneously Every Six Months. CPMS ID 49335, IRAS 1005048. Funder: FHI 360, USA. Participating sites: NHS Ayrshire & Arran and Lothian.
- ❖ **OASIS 4.** A double-blind, randomized, placebo-controlled multicentre study to investigate efficacy and safety of elinzanetant for the treatment of vasomotor symptoms caused by adjuvant endocrine therapy, over 52 weeks in women with, or at high risk for developing hormone-receptor positive breast cancer. CPMS 49518. Bayer AG. Sites: NHS Grampian and Greater Glasgow & Clyde.

Recent Commercial Feasibilities circulated to Health Boards

- ❖ **Exeltis LR-203.** A multicentre, phase II, dose finding, double-blind, randomized clinical trial to assess the efficacy and safety of LVDS 75 mcg/day and LVDS 125 mcg/day for the management of moderate to severe pain associated with endometriosis versus placebo after 4 medication cycles. CRO: Scope International.
- ❖ **A Phase 2, randomized, observer-blind, placebo-controlled study to evaluate the reactogenicity, safety, and immunogenicity of mRNA-1345, an mRNA vaccine targeting respiratory syncytial virus, in pregnant women, and safety and immunogenicity in infants born to vaccinated mothers.** Sponsor: Moderna.
- ❖ **Feasibility study: Use of a home monitoring device for high-risk patients with pre-eclampsia.** Sponsor: Heartfelt Technologies Ltd.

Your good news stories, queries, feedback, are always welcome:
Abha (abha.maheshwari@nhs.scot), NRS Clinical Research Lead, or
Txaro (maria.amezaga@nhs.scot), NRS Champion Support Manager

Please keep sending us your Good News Stories!

Which good news stories do your teams have to share?

First patients to trials, recruiting to difficult trials or completion of difficult trials to Target, Key Studies, Findings, Awards/achievements of local PI/CI/team members, collaborations, working with NIHR in cross border studies, bringing/ opening of Studies in Scotland.

Anything that goes on behind the scenes of recruitment numbers, overcoming challenges, achievements, etc.

FUNDING OPPORTUNITIES

CSO Innovation Academic Fellowships

Cohort 3 of the Innovation Fellowship Scheme will launch in August.



CHIEF
SCIENTIST
OFFICE



This cohort will be the same format as Cohort 2 and will provide the opportunity for clinicians early in their career to undertake a higher degree (MD or PhD). Up to 3 places will be available across Scotland. Anticipated timescales: Applications Open – August 2023; Applications Close – mid-October 2023; Interviews – January 2024; Fellowship starts – August 2024 (perhaps earlier depending on any training requirements and supervisor availability).

Information on current Innovation Fellowship cohorts is available [here](#).

NIHR Programme Grants for Applied Research (PGfAR) - Competition 42

NIHR PGfAR Competition 42 is inviting Stage 1 applications for research proposals to develop individual programmes of applied health research. Open: 07 June 2023, Closes: 13:00 on 02 August 2023.

[Programme Grants for Applied Research - Competition 42 | NIHR](#)

NIHR | National Institute for Health and Care Research

Please note in the Tips for applying: 'All NHS bodies and other providers of NHS services in England may propose programmes'. However, 'It is possible that the **academic partner could be a university outside England**, if an appropriate case is made in the application' [Tips for applying to Programme Grants for Applied Research | NIHR](#)

Reproductive Health and Childbirth Studies

For an update of Active Studies in Scotland, Non-commercial (Eligible/Extended review) and Commercial, per Health Board, please follow this [link](#).

In the NRS RH&C [webpage](#), Portfolio studies are highlighted in the [Study Portfolio section](#).

RH&C Newsletters can be found [here](#).

For information about studies in the portfolio please contact Abha (abha.maheshwari@nhs.scot) or Txaro (maria.amezaga@nhs.scot)

