Form: Syphilis and chancroid referral form

Form (B3) for the serology and molecular detection of Treponema pallidum.

MHRA releases guidance in collaboration with Health Canada to improve patient safety in clinical trials through improving the quality of Development Safety Update Reports

News story

The Medicines and Healthcare products Regulatory Agency (MHRA) and Health Canada have published guidance to improve the safety of patients in clinical trials through improved quality of the periodic safety reports known as Development Safety Update Reports (DSURs).



The Medicines and Healthcare products Regulatory Agency (MHRA) and <u>Health</u> <u>Canada</u> have jointly published <u>new guidance to improve the safety of patients in clinical trials</u> through improved quality of the periodic safety reports known as Development Safety Update Reports (DSURs). The guidance applies to both marketed and non-marketed medicines that are undergoing clinical trials.

Director of Licensing Division at MHRA Dr Siu Ping Lam said:

This guidance will improve the safety surveillance of clinical

trial participants in the UK.

We are committed to working with international partners to increase the quality of the Development Safety Update Reports submitted to regulators.

This collaboration highlights the leading role we take in ensuring the safety of clinical trials globally.

DSURs review the safety of medicinal products used in clinical trials and are produced every year. At present, even though trial sponsors will have conducted assessments regarding safety concerns, these detailed safety assessments are not always included in the DSUR. This makes it difficult for some regulators to find out if all safety concerns have been thoroughly investigated and whether appropriate measures have been taken to mitigate the risks associated with the use of the investigational medicinal products during a trial.

This guidance will improve transparency and ask sponsors to explain in the region-specific information section how they assessed the data included in the DSUR. The guidance builds on relevant existing international standards, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance E2F, the Council for International Organizations of Medical Sciences (CIOMS) Working Group VII as well as each country's relevant clinical trial legislation.

By increasing DSUR transparency requirements globally, patients' safety is safeguarded, and regulators can monitor how safely medicines are being investigated. This joint publication with Health Canada reflects the UK effort to demonstrate how international collaboration contributes to international research, patient safety and global public health.

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£500m firepower upgrade for Type 45 destroyers

Supporting over 100 highly-skilled jobs in Bristol, Stevenage, Gosport and Bolton, the two contracts will develop the cutting-edge air defence systems of the Type 45 destroyers.

MBDA UK has been awarded an 11-year contract to integrate the Common Anti-Air Modular Missile (CAMM) programme, often referred to as Sea Ceptor, into the

Type 45 destroyers' Sea Viper weapon systems. In addition to this, a 10-year contract with Eurosam will provide a refresh of the Aster 30 missiles system that are currently in use.

Minister for Defence Procurement, Jeremy Quin said:

Enhancing our destroyer capabilities, this investment reaffirms our commitment to equip the Royal Navy with the most advanced and powerful defensive systems.

This upgrade ensures the Type 45 remains hugely respected by naval fleets across the globe and secures highly-skilled jobs and investment.

Announced by the Prime Minister last November, Defence has received an increase in funding of over £24 billion across the next four years, focussing on the ability to adapt to meet future threats. Outlined further in the Defence Command Paper, this investment to upgrade the Type 45 destroyers will boost the lethality of the surface fleet. Currently, the Type 45 destroyers use a combination of short-range Aster 15 and long-range Aster 30 anti-air missiles to engage and destroy enemy threats. To facilitate the introduction of CAMM, a new 24-missile CAMM silo will be added in front of the current 48-missile Aster 30 silos, therefore increasing the overall missile capacity of the vessels by 50 per cent. This will result in a total capacity of 72 anti-air missiles per destroyer.

Royal Navy Fleet Commander, Vice Admiral Jerry Kyd CBE said:

These programmes will provide an exceptional capability to the front line, ensuring the RN remains poised to defend the surface fleet, and most importantly the Carrier Strike Group, against complex air threats both now and into the future.

CAMM also provides a means to accurately and effectively engage small, fast

inshore attack craft, hovering helicopters and low-speed targets alongside defeating their more traditional high-speed air targets.

The Aster 30 missile system refresh is a tri-national sustainment and enhancement contract between the UK, France and Italy which includes investment in a dedicated UK embodiment facility at Defence Munitions in Gosport, Hampshire.

DE&S CEO Sir Simon Bollom said:

The introduction of the UK produced CAMM missile in conjunction with the current Aster 30 missile will provide the Type 45 with a significant uplift in anti-air capability into the future as the Type 45 delivers the backbone of air defence to the Royal Navy's Carrier Strike Group.

The Royal Navy's Type 45 destroyers are among the most advanced in the fleet and carry out a range of activity, including defence from air attack, counter-piracy operations and providing humanitarian aid.

The first Type 45 destroyer is expected to have been overhauled by summer 2026.

Call for bids: British High Commission in Malta's Bilateral Programme Fund 2021-22

World news story

The British High Commission in Malta (BHC) is currently accepting proposals for innovative projects, with concrete objectives and measurable policy outcomes.



The British High Commission will run a competitive bidding process in order to ensure we use our allocation for high quality projects that deliver maximum impact and value for money.

The project funds are designated to support links between the UK and Malta in several priority areas through small—scale, high-impact project interventions (up to €20,000).

Proposals should be related to one of the following policy areas:

- environment and climate change
- open societies and media freedom
- strengthening rule of law and justice

We are looking for projects that deliver real, measurable results in support of the abovementioned priorities in these countries and are particularly interested in proposals aimed at the following objectives:

- support delivery of ambitious environmental targets and plans ahead of COP26 and beyond, including technical support and capacity building to institutions, businesses and youth working on climate issues
- support delivery transitions to clean growth in Malta's economy
- develop responsibility in government, society and business to take action on the impact of climate change on the environment and biodiversity
- support media freedom, including strengthening of responsible journalism, fighting misinformation and improving the enabling environment in which freedom of the press is protected and respected

- promote responsibility of society, business and government working together, including through Public-Private Partnerships (PPP) to prevent organised crime including such as international financial crime, Modern Slavery and Human Trafficking (MSHT) and Cyber Crime
- support protection of victims of crime, including MSHT, domestic and gender based violence and exploitation.
- support a robust and independent legal community by engaging with young lawyers with a focus on criminal law to share best practice, mentoring and leadership development

Who may bid

In order to be eligible, your organisation or agency must be a legal entity, commercial company, a registered non-governmental (NGO) or governmental organisation, and must demonstrate:

- proof of legal registration
- previous experience in delivering and managing projects
- preferably previous experience working with international agencies/organisations
- the capacity to deliver at least 75% of the proposed project activity by mid-December 2021

How to bid

Proposals should be presented by 19 July 2021, using the <u>Concept Bid Form</u> (ODT, 27.8KB)

Each institution may submit up to a maximum of 2 proposals.

Only short-listed applicants will be asked to submit a full <u>Project Proposal Form</u> (ODT, 35.8KB) and an <u>Activity Based Budget</u> (ODS, 8.33KB) by 31 July 2021.

Please send all project documents to bhcvalleta@fcdo.gov.uk

In the subject line of the email, please indicate "BHC Projects NAME OF ORGANISATION" and include the project title. Please send one email per proposal.

Date	Activity
5 July	Call for bids
19 July	Deadline for project implementers to send Concept Bid forms
19—23 July	/Embassy's Projects Board to revise and sift eligible proposals
23 July	Follow-up with pre-selected candidates
31 July	Deadline for candidates to send the Project Proposal Form and the Activity Based Budget

Bid guidance

- projects are funded for delivery during a single financial year, running from 1 April 2021 to 31 March 2022, with no expectation of continued funding beyond this period
- concept notes must outline how budgets are to be spent, with a clear consideration of providing value for money
- project proposals must include a communications strategy on how the project will be visible in country.

Attachments

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Update to Parliament on self-isolation rules

Mr Speaker, with permission, I'd like to make a statement on COVID-19 and our progress down our roadmap to freedom.

Freedom is in our sights once again, thanks to the protective wall of this country's vaccination programme and the huge advances we've made in getting this virus under control.

Yesterday, I stood at this Despatch Box and set out the details of what Step 4 in our roadmap will mean for this nation.

After the arduous 18 months that we've all endured, it was so wonderful to describe a world where we no longer have to count the number of people we're meeting, where theatres and stadiums are bustling with people once again and where care home residents are able to see loved ones without restrictions.

I understand that some people are cautious about the idea of easing restrictions. But we must balance the risks.

The risks of a virus that has diminished, but not defeated, against the risks of keeping these restrictions, and the health, social and economic hardship that we know they bring.

This pandemic is far from over, and we'll continue with caution. But we're increasingly confident that our plan is working, and that we can soon begin a new chapter based on the foundations of personal responsibility and common sense rather than the blunt instrument of rules and regulations.

Today, Mr Speaker, I'd like to provide an update on another area where we're

able to ease restrictions: the rules on self-isolation.

Self-isolation has played a critical role in helping us to get this virus under control, by denying the virus the human contact that it needs to spread. And I'm so grateful to the many, many people all across the UK, who have selflessly done their duty, making sacrifices so we can keep the virus at bay.

Even though we've done everything in our power to support the people who've had to self-isolate and yesterday we announced we'll be extending our financial support until September I'm fully aware of how difficult it's been. And that it's meant people missing out on precious moments and spending time apart from loved ones.

But we can take hope from the fact that science has shown us a solution, just as it's done so many times throughout our fight against this virus.

And that solution is our vaccine, which we know offers huge protection.

The latest data from PHE shows that our vaccination programme has saved over 27,000 lives and has prevented over 7 million people from getting COVID-19 and it shows that both doses of a COVID-19 vaccine can reduce symptomatic infection by almost 80 per cent.

This protective wall, because that's what it is, means the odds have shifted in our favour, and we can look afresh at many of the measures that we've had to put in place.

This is especially important when almost two thirds of adults - 64 per cent - have had both doses of a vaccine, and so have got the maximum protection on offer.

As a result, we will soon be able to take a risk-based approach, that recognises the huge benefits that vaccines provide, both to the people who get the jab and to their loved ones too.

So, from the 16th of August, when even more people will have the protection of both doses and when modelling suggests the risk from the virus will be lower, anyone who's a close contact of a positive case will no longer have to self-isolate, if they've been fully vaccinated.

If someone gets their second dose just before, or after, the 16th of August, they'll need to wait until two weeks after they get the second jab to benefit from these new freedoms so the vaccine has time to build the maximum possible protection.

As we make this change, we'll be drawing on the huge capacity we've built for testing and sequencing, and advising close contacts who are fully vaccinated to take a PCR test as soon as possible so they can get certainty about their condition.

Of course, anyone who tests positive will have to self-isolate, whether they've had the jab or not.

This new approach means we can manage the virus in a way that's proportionate to the pandemic, while maintaining the freedoms that are so important to us all.

As Honourable Members will be aware, we're not currently offering vaccines to most people under the age of 18. So, we've thought carefully about how we can make sure young people get the life experiences that are so important to their development while at the same time keeping them safe from this deadly virus.

In line with the approach for adults, anyone under the age of 18, who is a close contact of a positive case, will no longer need to self-isolate.

Instead, they'll be given advice about whether they should get tested, dependent on their age, and they'll need to self-isolate if they test positive.

These measures will also come into force on the 16th August, ahead of the Autumn school term.

I know that people will have questions about what these changes, and Step 4 of our roadmap, means for schools and colleges and my Right Honourable Friend, the Education Secretary, will be updating the House immediately after my statement.

We're also looking at the self-isolation rules for international arrivals so we can remove the need for full vaccinated individuals to isolate when they return from amber list countries and the Transport Secretary will update the House later this week.

Mr Speaker, step-by-step, and jab-by-jab, we're replacing the temporary protection of the restrictions with the long-term protection of a vaccine.

So we can restore the freedoms that we cherish, and the experiences that mean so much to us all.

Let's all play our part, to protect ourselves and to protect others, as we enter these crucial few weeks. So that in this battle between the vaccine and the virus, the vaccine will prevail.

I commend this statement to the House.