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WHITEPAPER

UK: Innovative Devices Access Pathway (IDAP) summary

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Introduction:

The Innovative Devices Access Pathway (IDAP) is to fasten the development and integration of cost-effective medical devices in to UK. The Innovative Devices Access Pathway (IDAP) pilot is initiated with £10 million funding from UK government to bring new technologies and solutions to the National Health Service (NHS) for helping the clinical needs which are not met.

The aim of IDAP is to enable and improve patient access to innovative and transformative medical devices and to test the main elements of the pathway to provide informative learning and feedback to build the future IDAP.

Eligibility:

- The product must be a medical device.
- The lead applicant must be a legal entity with the rights to market their health product in the UK.
- For early-stage health technologies, organisations must demonstrate a proof of concept evidenced by data from a near final prototype. According to NICE 'near final' prototype means, the development spread stage may include: Operational prototype developed, Design verification / Laboratory studies conducted (with prototype), Performance evaluation study started, in progress or concluding (with prototype), Pre-clinical studies started, in progress or concluding, Clinical investigation study started, in progress or concluding
- The applicant must be intending to market the health product in the UK and intend to obtain regulatory authorization.
- Applicants are expected to have identified clinical investigation sites and ideally have signed agreements in place. A signed letter of intent from the study site(s) with estimated timelines of when the study is expected to start, and its duration is acceptable.
- The applicant must commit to working with the IDAP partners to create a Target Development Profile.
- Organisations must have a recognised quality management system in place. Whilst certification is not mandatory, the system must satisfy the requirements of ISO 13485 or equivalent. When making the application, applicants were asked to provide detimproails of their formalised QMS along with when it was put in place and upload documents, for example, flow-charts, that demonstrate the maturity of the system. QMS system should go across the development life cycle of the product.

Not eligible:

- Drug medical device combination products.
- Legal entities headquartered or operating out of UK.

Criteria:

1. **Life-threatening or seriously debilitating condition with significant patient need.**
    - The product should address a potentially life-threatening or seriously debilitating condition.
    - The product should address an unmet clinical need.
    - Applications should be supported by at least one individual in a relevant health and/or care organisation or network.

2. **Innovative and transformative product.**
    - The product should be either new or a novel modification of existing technologies.
    - There are no solutions which fulfil the same clinical need and have regulatory approval in the UK.
    - The use of the device in the healthcare system has the potential to be transformative.

3. **The product will provide system wide benefit.**
    - The product will be widely adopted and is sustainable.
    - The product has potential to be cost effective.

4. **The technology helps to address one of the following Life Sciences Vision's Healthcare Missions:**
    - Improving translational capabilities in neurodegeneration and dementia.
    - Enabling early diagnosis and treatments, including immune therapies such as cancer vaccines.
    - Treatment and prevention of cardiovascular diseases and its major risk factors, including obesity.
    - Reducing mortality and morbidity from respiratory disease in the UK and globally.
    - Addressing the underlying biology of ageing.
    - Increasing the understanding of mental health conditions, including work to redefine diseases and develop translational tools to address them.

Improvements on existing technologies which require regulatory approval for the UK market will be acceptable to the IDAP process, if the product meets the IDAP pilot criteria. The development of diagnostic tools to select patients for existing drugs is also in scope if all criteria are satisfied.

IDAP partners are:

- Department of Health and Social Care (DHSC)
- Health Technology Wales (HTW)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- National Health Service England (NHSE)
- National Institute for Health and Care Excellence (NICE)
- Office of Life Sciences (OLS)
- Scottish Health Technologies Group (SHTG)

Successful applicants will be able to access the tools to expedite the development and integration of their new device into the UK market. The MHRA will offer support with testing and regulation of the products, while NICE will conduct a feasibility study of the product and facilitate its integration into the UK public health system. Successful applicants will receive non-financial support from the expert's team to develop a product specific Target Development Profile (TDP) roadmap that includes.

- Quality management system support
- System navigation advice
- A fast-tracked clinical investigation
- Joint scientific advice with partners
- Support with Health Technology Assessments (HTA) for product realization and adoption

- Safe-harbour meetings to discuss NHS adoption
- Exceptional use authorization granted by the MHRA, provided necessary safety standards are met.

The IDAP pilot phase has been restricted to 8 technologies/devices to ensure the selected products may get maximum benefit from their inclusion on the pathway and to enable comprehensive insights and knowledge to be integrated into the future IDAP. The learnings from the IDAP pilot and other initiatives within this area will inform development of a rules-based pathway in the longer term. To ensure diversity in technologies selected for the pilot, partners, with expert input, will take a portfolio approach to selecting the final projects.

The IDAP partners are exploring options with the Health Innovation Networks (HINs), on how they can support the pathway. Manufacturers must go through UK Conformity Assessment with an Approved Body to receive UKCA status. All technologies will be subject to NICE's standard topic selection and routing process to determine if are they eligible for HTA. Technologies selected for IDAP would have access to tools such as joint scientific advice and the HTA access forum to better support them with their evidence generation plans, HTA readiness, and their overall market access strategy.

Timeframes for placing IDAP product on the UK market under EUA before manufacturers need to apply for regulatory authorisation with a UK Approved Body will be product specific and included as a condition of granting the Exceptional Use Authorisation (EUA).

Security and confidentiality:

The IDAP Delivery Group will be able to access the data submitted in the application form to select technologies for the IDAP pilot. The MHRA IDAP Operations manager will ensure access is kept up to date by restricting access to the application form on a secure shared digital platform. Those who have access will be aware of their obligations and responsibilities when handling personal and confidential information. They are subject to employment, contractual and other professional obligations regarding confidential and official information, both during the IDAP process and afterwards.

All personal and confidential information is stored securely to prevent loss or inappropriate access. The MHRA will hold the personal information provided in this form and use it for the purpose of identifying who the application belongs to and to contact this individual regarding IDAP pilot activities. Information will be shared with the partners through a secure shared digital platform. If any new partner is identified, applicant will be contacted to inform of this and check whether applicant is happy for information to be shared with them. Personal data will not be shared with any other third party other than the data processors who act only upon our instructions. Any specific requests from a third party to share the personal data with them will be handled in accordance with data protection law. The MHRA will process the personal data in accordance with the DPA and UK GDPR and in the majority of circumstances this will mean that the personal data will not be disclosed to third parties. The partners will adhere to relevant institutional confidentiality and non-disclosure agreements.

Registration and evaluation:

To join the program, applicant must complete the IDAP pilot application via GovForms using a recommended browser.

Applicant must complete the form in one session as progress cannot be saved. To prepare evidence in advance, applicant can download a template of the form. The correct word limit for criterion two is 300 and should upload a single zip file for each page that needs an upload.

Upon completion of the web form applicant will receive confirmation of the submission and a unique IDAP pilot reference number. This number should be quoted in any enquiries. Questions or concerns about the IDAP pilot should be sent to email IDAPEnquiries@mhra.gov.uk.

The IDAP pilot was launched on 19 September 2023 and run until 1 November 2023 17:00 GMT, to give applicants more time to complete their applications. IDAP pilot outcomes will be communicated in December 2023. Target Development Profile engagements will start from January 2024.

All eligible applicants will be evaluated through a panel of experts. The panel will evaluate the applications according to which products are likely to receive the most benefit from the expertise and tools offered in the pilot. Applicants will receive updates about their entry via the email address they provided on their application. Organisations and individuals can submit multiple applications with a separate application per device. Edits cannot be made to a submission after it has been submitted. If applicants wish to amend their application after submission and before the application window closes, email IDAPEnquiries@mhra.gov.uk stating that they wish to withdraw the initial application, and submit a new application form. Applicants can withdraw their application by sending a written request to IDAPEnquiries@mhra.gov.uk stating that they wish to withdraw application. There is no fee for application or participation in the IDAP pilot.

Products coming through the IDAP pilot can be considered for exceptional use authorisations that will allow them to be placed on the whole UK market. Applications are not prioritized by location. The IDAP is open to UK and international commercial and non-commercial developers with new health technology solutions. The MHRA can exceptionally authorise medical devices for both the GB and NI markets under certain conditions. This means that products coming through the IDAP pilot can be considered for exceptional use authorisations that will allow them to be placed on the whole UK market.

Conclusion:

The IDAP has the potential to transform health outcomes and to increase the adoption of innovative technologies in the UK. IDAP is similar to the Innovative Licensing and Access Pathway (ILAP) of medicinal products and the medical devices industry is expecting a similar framework for innovative devices.

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