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Exploring scenarios of use and integration pipeline of Elecsys® GAAD, a clinical algorithm for the early detection of Hepatocellular Carcinoma (HCC) in routine practice

Principal Investigator:
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Co-investigators:
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Dr ShanShan Zhou, (Consultant- PPIE Lead).

Introduction: We would like to invite you to participate in a project that is being run by NIHR London In-vitro Diagnostics Cooperative based at Imperial College London. Before you decide whether to take part, it is important that you understand why the project is being done and what it will involve. This information sheet covers these issues – please take time to read it carefully and discuss it with others if you wish.

- You are invited to participate in a study to gather insights and feedback on the barriers, and opportunities in the adoption of a **Elecsys® GAAD, a clinical algorithm for the early detection of Hepatocellular Carcinoma (HCC) in routine practice**

- You will be asked to participate in one or both of the following studies:
    - A one-to-one remote interview to discuss the key stakeholders in the HCC pathway. The interview will last 30 minutes.
    - a one-to-one remote interview to discuss current HCC treatment pathways. The interview will last approximately 30-45 minutes.

- Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether you wish to take part.

Thank you for reading this.

- **What is the purpose of the study?**

The NIHR London In-vitro diagnostics will support the integration of Elecsys® GAAD, a clinical algorithm for the early detection of Hepatocellular Carcinoma (HCC) in routine practice developed by Roche Diagnostics. Within the 18-month project, we will conduct qualitative studies to understand barriers to adoption and integration strategies of the new device. We will achieve this by liaising with key stakeholders through semi-structured interview with healthcare professionals. We aim to gather insights on the expected integration pathways and implications in the use of the new device. The findings from this study will help establish the ideal scenarios of use and implementation guidelines.

- **Why have I been invited?**

  We are looking for healthcare professionals, who have relevant experience in the HCC treatment pathways.

- **Do I have to take part?**

  It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. The consent form can be electronically signed or hand signed and a copy sent to the researcher. If you decide to participate, you are free to withdraw at any time and without giving a reason. If you decide to withdraw from the study, all the identifiable data collected about you will be withdrawn. Data which is not identifiable to the research team may be retained. You can decide to participate in both interviews.

- **What will happen to me if I take part?**

You will be asked to provide non-identifiable information about key stakeholders in the HCC treatment pathways. You will be asked to provide your personal e-mail address if you wish to be forwarded the results of the study. One-to-one interviews will be conducted remotely (Microsoft Teams). You will be asked to provide information about current processes and

practices in the HCC treatment pathways. Upon consent, the interviews will be audio and video recorded. Both the recording and transcription files will be stored on an Imperial college password-protected secure server. Interview recordings will only be accessed by the named members from the NIHR London IVD and deleted after transcription.

Your answers will be kept pseudo-anonymous, which means that we will associate and ID number to your data and identifiable details will be not disseminated and stored on secure Imperial College London servers. This will be the extent of your involvement.
We are not envisaging financial incentives for participants who participate in the Study I.
Participants who take part in Study II will be offered an honorarium of £50 to be paid via a non-payroll form (NPF).

Participants who decide to withdraw from the study will not receive financial incentives.

- **What are the possible disadvantages and risks of taking part?**

  The organisers do not anticipate any harm to occur because of participating in the interview. The interviews will not cover topics of sensitive nature. The only potential risk involved in taking part in this study is the potential risk of a breach of confidentiality. To minimise this risk, we will adhere to GDPR/DPA 2018 and Imperial College London policies.

- **What are the possible benefits of taking part?**

There is no intended direct benefit for yourself however the information that you provide might help to improve existing tools and processes, leading to better use of the NHS resources. You will have the opportunity to collaborate with NIHR London IVD co-operative on this study. This might include working together on research publications and presentations.

- **What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Prof Peter Buckle (p.buckle@imperial.ac.uk) If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team.

- **What will happen to the results of the research study?**

The results will be analysed, and findings might be published in peer-reviewed scientific journals and/or the NIHR London IVDC website. If you would like to be notified about the publication date and journal, please contact a member of the team, who will be able to assist you further (see contact details below). As mentioned above, publications will not include identifying information.

- **Who is organising and funding the research?**

Imperial College London is the sponsor for this study. We are co-applicants of an SBRI project (ref. 30719) - NHS cancer Programme Competition 2. The grant fund will cover the research expenses.

- **Who has reviewed the study?**

This study was given approval by the Head of Department (Professor Vassilos Papalois) and Research Governance Integrity Team (RGIT).

Contact for Further Information

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If there is anything that is not clear or if you would like more information please feel free to contact the following researchers:

Dr Massimo Micocci
NIHR London IVD
m.micocci@imperial.ac.uk

Thank you for taking part in this study. *A copy of the written information and signed Informed Consent form will be given to the participant to keep.*

How will we use this information about you?

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has been completed in relation to primary research data

The study is expected to finish in May/2024.

For more information / confirmation regarding the end date please contact the study team, see 'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED' for contact information.

We will need to use information (including personal data and data created as part of the study) from you for this research project.
This information will include:

- your contact details if interested in taking part in the interview (name and email address(es);
- Basic demographic social information, including job role and setting and years of experience in that role

People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique study number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), (both organisations / Imperial College London) rely/relies on "scientific or historical research purposes or statistical purposes.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data-sharing agreement with the recipient research partner that incorporates UK-approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring the accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

- the following Research Collaborators / Partners in the study (NON OPTIONAL IF THIRD PARTIES INVOLVED OR EXPECTED);
  - The University of Manchester – final reports and pseudonymised data.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead, you will be identified by a unique study number with any sample analysis having the potential to generate personal data.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.
We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.
If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your data will be securely saved on an encrypted device, owned by Imperial College.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information:

by asking one of the research team
by sending an email to p.buckle@imperial.ac.uk, or
by ringing us on +44 (0)20 3312 6532

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to p.buckle@imperial.ac.uk, or by ringing us on +44 (0)20 3312 6532.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.