



### Application Form to Access the PathLAKE Data Lake

This application is intended for the use of data held in the PathLAKE data lake for research and commercial purposes.

Applications are welcomed from NHS organisations, academia and industry.

The information requested in this form is necessary in order to document your request for data correctly.

#### Guidance for applicants:

- A. Type the document.
- B. Ensure that the “lay summary” (Page 4, Research Information section) is written in plain English, without unexplained acronyms or medical terminology. Failure to provide a comprehensive and easy to understand lay summary will result in a request for a rewrite of the summary prior to its acceptance for consideration.
- C. Patient identity is confidential and all the data in the data lake has been de-identified and is held in anonymised form. Access to the data is provided in proportion to the task to be accomplished. Access to data is dependent on PathLAKE retaining all annotations or other aspects of data enrichment generated by the project for the benefit of future research. If you wish to apply to have this restricted, you need to complete the relevant section of the form. Data will be shared free of charge to PathLAKE consortium members and UK SMEs<sup>1</sup> only. A pricing strategy is in development for provision of data to NHS, academic and commercial institutions outside of the consortium.
- D. The PathLAKE data lake is authorized by South Central - Oxford C REC (Ref 19/SC/0363) to provide data to researchers. Researchers receiving data from PathLAKE are NOT required to have approval from NRES for the use of this data as data will be provided anonymously. However, researchers must be able to satisfy the PathLAKE Access Committee that the project they submit is both ethically and scientifically valid. If the applicant is already in possession of NRES approval for their project, a copy of the NRES letter should be supplied with this application. It is the applicant’s responsibility to comply with data protection legislation and/or other appropriate laws that cover medical research.

Where feasible, data research will be performed inside the PathLAKE firewall. Where this is not feasible, the required data will be copied and transferred to the applicant in an appropriate format. The applicant is expected to cover the costs incurred in this process.

- E. Please email the completed application form to [PathLAKE@uhcw.nhs.uk](mailto:PathLAKE@uhcw.nhs.uk)
- F. The PathLAKE Access Committee will review applications and aims to provide a decision within one calendar month from receipt of a valid submission. For applications that require further review/information, the Access Committee will aim to provide a decision within eight weeks of initial receipt.

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<sup>1</sup> As set out in the European Commission Recommendation of 6 May 2003, an SME is a business with fewer than 250 employees, a turnover of less than €50 million or a balance sheet total of €43 million.



**PathLAKE**  
Computational Pathology Excellence



**University Hospitals  
Coventry and Warwickshire**  
NHS Trust

**Lead Applicant**

Name: .....

Title: .....

Institution: .....

Address: .....

.....

.....

Post Code: .....

Country: .....

Phone: .....

Email: .....

**Contact person, if different from above:**

Name: .....

Title: .....

Phone: .....

Email: .....

<b>Organisation Details</b>	✓
NHS Trust	
Other Healthcare Institution	
UK University	
Overseas University	
Corporate Business	
UK SME*	
Overseas SME*	

\* As set out in the European Commission Recommendation of 6 May 2003, an SME is a business with fewer than 250 employees, a turnover of less than €50 million or a balance sheet total of €43 million.





Invoice Information

Invoices will be sent to the address listed above. If you would like the original invoice to be provided by post to another location (e.g. your finance department), please enter contact details and address below.

Name: .....

Title: .....

Institution: .....

Address: .....

.....

.....

.....

Post Code: .....

Country: .....

Phone: .....

Email: .....

Research Information

1. If your project is supported by research funding, please indicate the source of funds for your proposed project. If this is Institutional Funding, please enclose a letter from your Head of Department indicating that funds and premises are available to complete your project.

**Funding Source**

*Enter details of funding source here*



**Period of Support**

*Enter period of funding support here*

- Please provide a short plain English summary (max 500 words) of the intended research and its benefit to patients. A plain English summary is a brief summary that has been written for members of the public and an interested audience rather than specialists. It should be written clearly and simply, without jargon and with an explanation of any technical terms that have to be included. Please note this information will be treated in strict confidence while under review. Lay Summaries of approved projects will be published on the PathLAKE website.**

*Enter a short lay summary here*

**If your project has already been reviewed as part of a grant funding application, you may omit section 3 below but please provide the scientific part of the grant application and the confirmation of approval for funding.**

- Please provide the title and a short research summary (2-4 pages of A4) of the proposed research on the samples you are requesting from the PathLAKE data lake. Use additional pages where necessary. Sufficient information should be provided to enable the PathLAKE Access Committee to determine the scientific validity of your study. Please fully justify the number and type of data requested and address ALL the headings below. This information will be treated in strict confidence.**

**3.1. Title**

*Enter title here*



**3.2. Introduction**

*Please include an overview of the state of the art in your proposed project area.*

*Enter introduction here*

**3.3. Hypothesis & Aim(s)**

*Please state the aim(s) of your project clearly.*

*Enter hypothesis and aims here*

**3.4. Experience of group and/or company carrying out analysis**

*Please provide information to indicate that your research group has experience in the techniques you intend to use, either by use of preliminary data from other work carried out in your group or by providing references to publications from your group/company that are relevant to this application.*

*Please include any relevant peer reviewed research publications by any members of your team in this section of the application.*

*Enter experience here*

**3.5. Methods**

*Please detail the methods you intend to use, indicating controls and the experimental design you will use where relevant include statistical information.*

*Enter methods here*

**3.6. Please provide evidence of any quality management system(s) you will be using (e.g. standard operating procedures, ISO standards)**

*Enter quality management evidence here*

**Data Requested**

**4. Please specify what data you require and the number of cases you wish to access. (e.g. 2000 cases of invasive ductal carcinoma of the breast.)**

*Include details of the whole slide image data and the meta-data required.*

**4.1. Number of cases and details of whole slide image data required:**

*Enter details here*

**4.2. Details of meta-data required;**

*Please specify e.g. demographic data (e.g. gender, year of birth), procedure type and year of procedure, diagnostic SMOMED code, tissue type, stain name (e.g. HE, HER2, ER, PR), scanner details (e.g. interface version, manufacturer, model name, etc.), pathology report (clinical details, macroscopic report, microscopic report, diagnosis field, etc.), blood test results or radiology reports.*

*Enter details here*



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### Commercial Products

5. Is the object of this research to develop a tool of commercial value?

YES

NO

If yes, has the proposal been submitted to the Medicines and Healthcare Regulatory Authority?

YES

NO

Please provide details:

*Enter details here*

6. Please provide a description of your product.

*Enter details here*

### Proposed Arrangements for Commercialisation

There are three commercialisable products which may be developed as potential outcomes from the research:

- (i) Whole slide images
- (ii) Annotated whole slide images
- (iii) Predictive algorithms created using data in (i) and (ii) above.

PathLAKE is required to generate a revenue stream from products that are developed from data in the data lake with this income being fed back to the NHS institutions within the PathLAKE consortium. A commercialisation strategy is being developed considering a number of income generation models including:

- (i) Payment of a lump sum on the provision of data
- (ii) Royalties on downstream income generated from future sales generated by a third party from the licensing of IP in the one or more of the three commercialisable products listed above.



## Agreement for Use of Data

The recipient agrees that the data provided by PathLAKE will be used only for the purposes specified in this application.

The recipient agrees not to attempt to obtain information identifying the individuals from whom the data was acquired.

The recipient agrees that it shall not sell any portion of the data provided, nor transfer any of the data supplied, and agrees to return all data provided back to PathLAKE when it is no longer required for the purpose provided.

The recipient agrees to provide, or grant permission to keep, any annotations, ground truth data, or any other addition to the data supplied which enriches the data for future researchers.

**Or**

The recipient agrees to provide, or grant permission to keep, any annotations, ground truth data, or any other addition to the data supplied which enriches the data for future researchers other than the following items:

*Enter details here*

These items, if within PathLAKE's possession, will be treated confidentially and will not be visible as part of the data lake.

Data is provided as a service without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. No provider of any data to the PathLAKE data lake accepts any responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use.

The recipient agrees to acknowledge the contributions of PathLAKE in all publications resulting from the use of this data.

The recipient agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of data from PathLAKE. It further agrees to indemnify and hold harmless PathLAKE and University Hospitals Coventry & Warwickshire NHS Trust from any claims costs, damages or expenses resulting from the use of the data provided. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.





**PathLAKE**  
Computational Pathology Excellence

**NHS**  
**University Hospitals**  
**Coventry and Warwickshire**  
NHS Trust

**BY MY SIGNATURE, I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT**

Signature: .....

Name: .....

Title: .....

Date: .....

UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTED ABOVE, THE PathLAKE ACCESS COMMITTEE WILL CONSIDER THIS REQUEST.

Specific questions about this application should be directed to:

Email: [PathLAKE@uhcw.nhs.uk](mailto:PathLAKE@uhcw.nhs.uk)

Tel +44 (0)2476 968582

PathLAKE Project Officer, PathLAKE Office, Room 20068, CSRL, University Hospitals Coventry & Warwickshire NHS Trust, Clifford Bridge Road, Coventry CV2 2DX.,

