## Clinical Trials Landscape in Oncology - Freedom of Information Request

To Whom It May Concern:

I hope this message ﬁnds you well. I am reaching out to gather crucial information regarding the pre- and current post-BREXIT clinical trials landscape in Oncology on a nationwide basis in the UK. Your expertise and insight from your current NHS hospital Trust that you represent, are invaluable in enhancing our understanding of the trends and challenges in this ﬁeld, so that appropriate recommendations could be made.

Before completing this survey, kindly check to ensure that your hospital(s) provide(s) systemic therapy for solid cancer (i.e. initiation of SACT and follow up of Oncology patients) in adults. If so, please proceed with this survey.

If your hospital does not provide systemic therapy for solid cancers, then please do not complete this survey and instead e-mail back to notify us and we will update our records accordingly.

Furthermore, we advise that whoever is designated to complete this survey should be in charge of, lead or co-ordinate the solid cancer, thus only Oncology (i.e. NOT haematological malignancies, not haem-onc) clinical trials department at your NHS hospital. Questions should be answered on behalf of the organisation.

In relation to this survey, we only aim to obtain data regarding systemic anti-cancer therapies (SACT) as investigational medicinal products (IMP). Examples of such therapies include chemotherapy, cellular therapies, biologics, hormonal therapy, targeted therapy, immunotherapy and other. This survey speciﬁcally enquires about interventional studies (e.g. studying the safety and/or eﬀicacy of novel treatments).

In the case of multi-phase trials, indicate the lower phase number. We request information from the following hospitals:

**England**: All

**Wales:**

* Velindre Cancer Centre
* South Wales Cancer Centre (Aneurin Bevan)
* Glan Clwyd Hospital (Betsi Cadwaladr)
* Ysbyty Gwynedd Hospital (Betsi Cadwaladr)
* Wrexham Maelor (Betsi Cadwaladr)

**Scotland:**

* Aberdeen Royal Inﬁrmary (Grampian)
* Beaston (the) West of Scotland Cancer Centre (Greater Glasgow & Clyde)
* Glasgow Royal Inﬁrmary (Greater Glasgow & Clyde)
* Inverclyde Royal Hospital (Greater Glasgow & Clyde)
* Stobhill General Hospital (Greater Glasgow & Clyde)
* University Hospital Crosshouse (Ayrshire & Arran)
* University Hospital Ayrshire (Ayrshire & Arran)
* University Hospital Monklands (Lankashire)
* Ninewells Hospital (Tayside)
* Perth Royal Inﬁrmary (Tayside)
* Queen Margaret Hospital (Fife)
* Victoria Hospital, Kirkcaldy (Fife)
* Edinburgh Cancer Centre, Western General Hospital (Edinburgh)
* Falkrik Royal Inﬁrmary (Fort Valley)

**Northern Ireland:**

* Belfast City Hospital (Belfast)
* Royal Victoria Hospital (Belfast)
* Antrim Area Hospital (Northern)
* Ulster Hospital (Southern Eastern)
* Craigavon Area Hospital (Southern)
* Altnagelvin Area Hospital (Western)

Note that the purpose of this survey is for academic research with the aim to publish the ﬁnal results. Final data will be collated. However, any outliers or notable results may be identiﬁable.

Please do not hesitate to contact us if you have any further queries. Thank you for your contribution.

**\* Name of person completing out this form:**

Angela Power

Wrightington Wigan and Leigh Teaching hospitals

**\* Full name of the hospital or NHS Trust (specify):**

Senior Oncology Research Nurse

**\* Your role at the hospital:**

Recruit and follow up patients

**\* Your involvement in oncology clinical trials:**

\* Is your hospital/ NHS Trust a Cancer Unit, Cancer Centre or Centre of Excellence in Cancer Care?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No | X |

\* 1.Ia What tumour groups do you treat with systemic anti-cancer therapy at your centre?

|  |  |
| --- | --- |
|  | Tick all that apply |
| Head & Neck (H&N) |  |
| Central nervous system (CNS)  |  |
| Skin/ Melanoma |  |
| Urology/ Renal  | x |
| Gynae-Onc  |  |
| Breast | x |
| Upper Gastrointestinal (UGI)  |  |
| Lower Gastrointestinal (LGI)  | x |
| Hepato-pancreatico-biliary (HPB)  |  |
| Cancer of unknown primary (CUP) Lung |  |
| Sarcoma |  |

\* 1.Ib Since 2010, for what tumour groups has your organisation had clinical trials involving systemic anti-cancer therapy? Select all that apply.

|  |  |
| --- | --- |
|  | Tick all that apply |
| Head & Neck (H&N) |  |
| Central nervous system (CNS)  |  |
| Skin/ Melanoma |  |
| Urology/ Renal  | x |
| Gynae-Onc  |  |
| Breast | x |
| Upper Gastrointestinal (UGI)  |  |
| Lower Gastrointestinal (LGI)  | x |
| Hepato-pancreatico-biliary (HPB)  |  |
| Cancer of unknown primary (CUP) Lung |  |
| Sarcoma |  |
| None of the above (ensure you do not tick any other boxes) |  |

\* 1.Ic In TOTAL, how many clinical trials (interventional Phase 0 - III) involving novel or novel combination or novel way of administering systemic anti-cancer therapies for solid cancers did you have in the Oncology department on 31 Dec in each year (provide a snapshot number) since 2010?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 3 |
| 2011 | 5 |
| 2012 | 3 |
| 2013 | 3 |
| 2014 | 5 |
| 2015 | 5 |
| 2016 | 6 |
| 2017 | 7 |
| 2018 | 7 |
| 2019 | 6 |
| 2020 | 6 |
| 2021 | 5 |
| 2022 | 9 |
| 2023 | 5 |

\* 1.Id Of the total number of clinical trials you reported in 1.Ic, how many were solely funded by the NHS and NIHR (thus excluding trials funded by charity, government research councils like MRC, academic institutions and commercial companies)?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 1 |
| 2011 | 1 |
| 2012 | 1 |
| 2013 | 1 |
| 2014 | 1 |
| 2015 | 0 |
| 2016 | 0 |
| 2017 | 0 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 1.Ie Of the total number of clinical trials you reported in 1.Ic, how many were PHASE 1 trials?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 0 |
| 2011 | 0 |
| 2012 | 0 |
| 2013 | 0 |
| 2014 | 0 |
| 2015 | 0 |
| 2016 | 0 |
| 2017 | 0 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 1.If Of the total number of clinical trials you reported in 1.Ic, how many were PHASE 2 trials?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 0 |
| 2011 | 0 |
| 2012 | 0 |
| 2013 | 0 |
| 2014 | 0 |
| 2015 | 1 |
| 2016 | 1 |
| 2017 | 1 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 1.Ig Of the total number of clinical trials you reported in 1.Ic, how many were PHASE 3 trials?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 3 |
| 2011 | 5 |
| 2012 | 3 |
| 2013 | 3 |
| 2014 | 5 |
| 2015 | 5 |
| 2016 | 6 |
| 2017 | 7 |
| 2018 | 7 |
| 2019 | 6 |
| 2020 | 6 |
| 2021 | 5 |
| 2022 | 9 |
| 2023 | 5 |

\* 1.Ih On a separate note, how many Phase IV trials did you conduct in each year at your hospital/ Trust?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 0 |
| 2011 | 0 |
| 2012 | 0 |
| 2013 | 0 |
| 2014 | 0 |
| 2015 | 0 |
| 2016 | 0 |
| 2017 | 0 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 1.Ii Of the total number of clinical trials you reported in 1.Ic, how many involved another procedure such as surgery or radiotherapy in combination with the trialed systemic anti-cancer therapy within the trial?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 0 |
| 2011 | 0 |
| 2012 | 0 |
| 2013 | 0 |
| 2014 | 0 |
| 2015 | 0 |
| 2016 | 0 |
| 2017 | 0 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 1.Ij Provide the total number of adult patients enrolled in phase I - III solid-cancer systemic anti-cancer therapy trials on 31 Dec of each year at your hospital/ Trust:

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 31 |
| 2011 | 24 |
| 2012 | 23 |
| 2013 | 6 |
| 2014 | 10 |
| 2015 | 30 |
| 2016 | 38 |
| 2017 | 28 |
| 2018 | 43 |
| 2019 | 33 |
| 2020 | 11 |
| 2021 | 9 |
| 2022 | 20 |
| 2023 | 38 |

\* 1.Ik In each year, how many new Phase I - III clinical trials did you open for recruitment?

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 0 |
| 2011 | 0 |
| 2012 | 1 |
| 2013 | 0 |
| 2014 | 2 |
| 2015 | 2 |
| 2016 | 1 |
| 2017 | 0 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 2.I Post-BREXIT, what regulatory changes have had the greatest impact on the initiation of oncology trials at your centre?

Following the O’Shaughnessy report, this enables sites to expect a quick set up of trials within 60 days

\* 2.II Post-BREXIT, what regulatory changes have had the greatest impact on the conduct/ continuation of oncology trials at your centre?

No major changes

\* 2.IIIa Post-BREXIT, have you observed any speciﬁc challenges related to regulatory compliance for initiating new oncology trials at your centre?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No | x |
| Unsure |  |

\* 2.IIIb If yes, please specify the regulatory challenges encountered:

NA

\* 2.IVa Have there been any notable changes in the regulatory reporting requirements for ongoing oncology trials post-BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No | x |
| Unsure |  |

\* 2.IVb If yes, please elaborate on the changes and their impact on trial conduct:

NA

\* 2.Va Have there been any changes in the timeline for regulatory approvals post-BREXIT for initiating new oncology trials?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No | x |
| Unsure |  |

\* 2.Vb If yes, please specify the nature of delays and their impact on trial initiation:

NA

\* 2.VI How has the communication and coordination with regulatory authorities changed post-BREXIT in the context of oncology trials?

No major changes noted

\* 2.VIa Have there been any new documentation or compliance requirements introduced post-BREXIT for ongoing oncology trials?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 2.VIb If yes, please provide examples of the additional documentation or compliance measures introduced:

NA

\* 2.VII How has the training and education of clinical trial staﬀ in your centre been impacted by regulatory changes post-BREXIT?

No Major changes

\* 2.VIIIa Have there been any changes in the requirements for informed consent processes for oncology trials post-BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No | x |
| Unsure |  |

\* 2.VIIIb If yes, please specify the nature of changes and their impact on the informed consent process:

NA

\* 2.IX How has the interpretation and implementation of Good Clinical Practice (GCP) guidelines evolved post-BREXIT in your centre?

Requirement now 3 yearly

\* 2.Xa Where staﬀ updated or educated on regulatory changes post- BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Yes | x |
| No |  |

\* 2.Xb If yes, explain how:

Communication from NIHR & HRA

\* 2.Xc If no, explain why not:

NA

\* 3.I In each year, how many Phase 0 - IV clinical trials did you have to discontinue due to a lack of funding? Comment on the funding sources aﬀected:

|  |  |
| --- | --- |
|  | Number of trials, n |
| 2010 | 0 |
| 2011 | 0 |
| 2012 | 0 |
| 2013 | 0 |
| 2014 | 0 |
| 2015 | 0 |
| 2016 | 0 |
| 2017 | 0 |
| 2018 | 0 |
| 2019 | 0 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |

\* 3.II Name all organisations, including your own, that sponsored and/or funded solid- cancer systemic-anticancer therapy trials at your centre in each year:

|  |  |
| --- | --- |
|  | Sponsors/ funders |
| 2010 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University,  |
| 2011 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University,  |
| 2012 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL |
| 2013 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL |
| 2014 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL |
| 2015 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL, Velindre NHS trust, Astra Zenica |
| 2016 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL, Velindre NHS trust, Astra Zenica, ICR |
| 2017 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL, Velindre NHS trust, astra Zenica, ICR |
| 2018 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL, Velindre NHS trust, Astra Zenica, ICR |
| 2019 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL, ICR |
| 2020 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, UCL, ICR |
| 2021 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, ICR |
| 2022 | Royal Marsden hospital, CRUK, Glasgow University, Medical Research Council, NIHR,Cambridge University, ICR |
| 2023 | Royal Marsden hospital, CRUK, NIHR, Cambridge University, ICR |

\* 3.III How has the funding landscape for oncology pharmaceutical trials at your centre changed post-BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Increased funding opportunities  |  |
| Decreased funding opportunities  |  |
| No signiﬁcant change |  |
| Not Sure | x |

\* 3.IV If there has been a change, please describe the main factors contributing to the shift in funding availability:

NA

\* 3.V How has the change in funding impacted the continuity of ongoing oncology pharmaceutical trials at your centre?

NA

\* 3.VI Are there speciﬁc types of trials more aﬀected by funding challenges (e.g., Phase 1, investigator-initiated trials, certain types of systemic anti-cancer drugs, combination therapies, for certain tumour groups)?

NA

\* 3.VII How has the uncertainty surrounding BREXIT impacted the willingness of funding organisations to support oncology trials?

|  |  |
| --- | --- |
|  | Tick one |
| Signiﬁcantly impacted |  |
| Moderately impacted |  |
| Minimally impacted |  |
| No impact |  |
| Not Sure | x |

\* 3.VIII Answering on behalf of your organisation, are there any speciﬁc policy changes that would enhance funding opportunities for oncology trials post-BREXIT?

NA

\* 3.IXa Have you explored alternative funding sources or strategies to mitigate potential funding challenges post-BREXIT? **Not Applicable**

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure |  |

\* 3.IXb If yes, please share details of any successful strategies or approaches implemented:

NA

\* 3.X To what extent have patient advocacy groups played a role in supporting or inﬂuencing funding for oncology trials post-BREXIT in or for your organisation?

NA

\* 3.XIa Have there been any changes in the criteria or preferences of funding organisations when considering proposals for oncology trials post-BREXIT? **Not Applicable**

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure |  |

\* 3.XIb If yes, please elaborate on the key changes in criteria or preferences:

NA

\* 4.I Comment on collaborative challenges that aﬀected or caused disruptions in the initiation or running of solid-cancer systemic anti- cancer therapy drugs:

|  |  |
| --- | --- |
|  | Collaborative Challenges |
| 2010 | Not sure to all years |
| 2011 |  |
| 2012 |  |
| 2013 |  |
| 2014 |  |
| 2015 |  |
| 2016 |  |
| 2017 |  |
| 2018 |  |
| 2019 |  |
| 2020 |  |
| 2021 |  |
| 2022 |  |
| 2023 |  |

\* 4.IIa Have there been challenges in maintaining international collaborations for oncology trials post-BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 4.IIb If yes, please identify the main collaborative challenges faced:

NA

\* 4.IIIa Have changes in regulatory requirements impacted international partnerships in oncology trials?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 4.IIIb If yes, please elaborate on the speciﬁc regulatory aspects causing challenges:

NA

\* 4.IVa In your experience, have collaborative challenges aﬀected the timeline and eﬀiciency of oncology trials?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 4.IVb If yes, please provide examples or instances where collaboration challenges led to disruptions in trial initiation or conduct:

NA

\* 4.Va At your current NHS hospital, have there been challenges in aligning international ethical standards and practices for oncology trials post-BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 4.Vb If yes, please elaborate on the speciﬁc ethical challenges faced and their impact on collaborative eﬀorts:

NA

\* 4.VI How has the exchange of trial-related data and information with international partners been aﬀected post-BREXIT?

NA

\* 4.VIIa In your organisation's experience, have there been any challenges related to diﬀerences in patient populations across international sites in oncology trials?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 4.VIIb If yes, please provide examples or instances where diﬀerences in patient populations posed challenges to collaborative eﬀorts?

NA

\* 4.VIII How has the exchange of expertise and specialised resources with international collaborators been aﬀected post-BREXIT?

unsure

\* 4.IX From your organisation's perspective, what strategies or initiatives could enhance international collaboration in oncology trials in the post-BREXIT era?

unsure

\* 5.Ia Have you become aware of or experienced any challenges related to the alignment of data privacy and protection regulations in international oncology trials post-BREXIT?

|  |  |
| --- | --- |
|  | Tick one |
| Yes |  |
| No |  |
| Unsure | x |

\* 5.Ib If yes, please elaborate on the speciﬁc challenges faced and any measures

NA

**Thank you for taking the time to complete this survey.**