Clinical Trials Landscape in Oncology - Freedom of Information Request 7780

To Whom It May Concern:

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.

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.

*	**Name of person completing out this form:**	Tumi Kaminskas
*	**Full name of the hospital or NHS Trust (specify):**	Salisbury NHS Foundation Trust
*	**Your role at the hospital:**	Head of Research
*	**Your involvement in oncology clinical trials:**	Sponsor duties

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

	Tick one
Yes	
No	√

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

	Tick all that apply
Head & Neck (H&N)	no
Central nervous system (CNS)	no
Skin/ Melanoma	no
Urology/ Renal	yes
Gynae-Onc	yes
Breast	yes
Upper Gastrointestinal (UGI)	yes
Lower Gastrointestinal (LGI)	yes
Hepato-pancreatico-biliary (HPB)	yes
Cancer of unknown primary (CUP) Lung	yes
Sarcoma	no
	Tick all that apply

* 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)	no
Central nervous system (CNS)	no
Skin/ Melanoma	yes
Urology/ Renal	yes
Gynae-Onc	yes
Breast	yes
Upper Gastrointestinal (UGI)	yes
Lower Gastrointestinal (LGI)	yes
Hepato-pancreatico-biliary (HPB)	yes
Cancer of unknown primary (CUP) Lung	no
Sarcoma	no
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	18
2011	18
2012	18
2013	15
2014	12
2015	8
2016	8
2017	7
2018	6
2019	7
2020	7
2021	7
2022	6
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	
2011	
2012	
2013	
2014	
2015	
2016	
2017	
2018	
2019	

2020	
2021	
2022	
2023	

* 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	8
2011	5
2012	4
2013	4
2014	3
2015	3
2016	2
2017	2
2018	2
2019	2
2020	2
2021	2
2022	2
2023	2

* 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	10
2011	13
2012	14
2013	11

2014	9
2015	5
2016	6
2017	5
2018	4
2019	5
2020	5
2021	5
2022	4
2023	3

* 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	
2011	
2012	
2013	
2014	
2015	
2016	
2017	
2018	
2019	
2020	
2021	
2022	
2023	

* 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	
2011	
2012	
2013	
2014	
2015	
2016	
2017	
2018	
2019	
2020	
2021	
2022	
2023	

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

	Number of trials, n
2010	6
2011	3
2012	2
2013	1
2014	2
2015	2
2016	4
2017	2
2018	1
2019	1
2020	1
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?

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

* 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	
Unsure	

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

	Tick one
Yes	
No	
Unsure	

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

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

	Tick one
Yes	
No	
Unsure	

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

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

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

	Tick one
Yes	
No	
Unsure	

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

regulatory changes post-BREXIT?

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

	Tick one
Yes	
No	
Unsure	

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

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

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

	Tick one
Yes	
No	

* 2.Xb If yes, explain how:

* 2.Xc If no, explain why not:

* 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	
2011	
2012	
2013	
2014	
2015	
2016	
2017	
2018	
2019	
2020	
2021	
2022	
2023	

* 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	
2011	
2012	
2013	
2014	

2015	
2016	
2017	
2018	
2019	
2020	
2021	
2022	
2023	

* 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	

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

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

* 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)?

* 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	

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

* 3.IXa Have you explored alternative funding sources or strategies to mitigate potential funding challenges post-BREXIT?

	Tick one
Yes	
No	
Unsure	

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

* 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?

* 3.XIa Have there been any changes in the criteria or preferences of funding organisations when considering proposals for oncology trials post-BREXIT?

	Tick one
Yes	
No	
Unsure	

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

* 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	
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	

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

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

	Tick one

Yes	
No	
Unsure	

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

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

	Tick one
Yes	
No	
Unsure	

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

* 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	

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

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

* 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	

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

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

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

* 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	

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

Thank you for taking the time to complete this survey.