*** Name of person completing out this form:**	Amanda McCairn
*** Full name of the hospital or NHS Trust (specify):**	Mersey and West Lancashire Teaching Hospitals NHS Trust
*** Your role at the hospital:**	Lead Research Nurse
*** Your involvement in oncology clinical trials:**	Lead Research Nurse

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

	Tick one
Yes	Yes, provides SACT therapy Nurse lead chemo day unit.
No	

*** 1.a 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	Yes
Urology/ Renal	Yes
Gynae-Onc	Yes
Breast	Yes
Upper Gastrointestinal (UGI)	Yes
Lower Gastrointestinal (LGI)	Yes
Hepato-pancreatico-biliary (HPB)	No
Cancer of unknown primary (CUP) Lung	Yes
Sarcoma	No

*** 1.b 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	No
Gynae-Onc	Yes
Breast	Yes
Upper Gastrointestinal (UGI)	No
Lower Gastrointestinal (LGI)	Yes
Hepato-pancreatico-biliary (HPB)	No
Cancer of unknown primary (CUP) Lung	No
Sarcoma	No
None of the above (ensure you do not tick any other boxes)	N/A

*** 1.c 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
2010	5
2011	8

2012	5
2013	6
2014	4
2015	4
2016	4
2017	2
2018	0
2019	0
2020	0
2021	0
2022	0
2023	0

*** 1.d Of the total number of clinical trials you reported in 1.c, 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
2010	1
2011	1
2012	1
2013	1
2014	1
2015	1
2016	1
2017	0
2018	0
2019	0
2020	0
2021	0
2022	0
2023	0

*** 1.e Of the total number of clinical trials you reported in 1.c, how many were PHASE 1 trials?**

	Number of trials
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.f Of the total number of clinical trials you reported in 1.c, how many were PHASE 2 trials?**

	Number of trials

2010	1
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.g Of the total number of clinical trials you reported in 1.c, how many were PHASE 3 trials?**

	Number of trials
2010	4
2011	8
2012	5
2013	6
2014	4
2015	4
2016	4
2017	2
2018	0
2019	0
2020	0
2021	0
2022	0
2023	0

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

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

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

*** 1.j 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
2010	23
2011	39
2012	32
2013	11
2014	7
2015	6
2016	7
2017	9
2018	0
2019	0
2020	0
2021	0
2022	0
2023	0

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

	Number of trials
2010	1
2011	2
2012	1
2013	1
2014	1
2015	1
2016	0
2017	0
2018	0
2019	0
2020	0
2021	0
2022	0

2023	0

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

N/A - did not conduct any oncology SACT trials after 2020. Mersey and West Lancashire Teaching Hospitals (MWL) do not sponsor any oncology trials, MWL take part as a site. All the regulatory requirements are conducted by the Sponsor.

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

No communication from EORTC trial centre since Brexit, trial has stopped but not been told don't collect data or continue.

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

	Tick one
Yes	
No	No
Unsure	

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

N/A

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

	Tick one
Yes	
No	No
Unsure	

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

N/A

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

	Tick one
Yes	
No	
Unsure	Mersey and West Lancashire Teaching Hospitals (MWL) NHS Trust do not sponsor any oncology trials. MWL take part as a site. All the regulatory requirements are conducted by the Sponsor.

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

N/A

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

Unsure - we are not a sponsor for studies therefore do not go through the regulatory authorities.

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

	Tick one
Yes	
No	
Unsure	Unsure

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

N/A

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

No noticeable changes, GCP conducted 2 yearly.

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

	Tick one
Yes	
No	No
Unsure	

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

N/A

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

Continue to refresh GCP 2 yearly as per hospital policy.

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

	Tick one
Yes	YES
No	

*** 2.q If yes, explain how:**

Via GCP training.

*** 2.r If no, explain why not:**

N/A

*** 3. 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
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.a 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	• CRUK • MRC • Eli Lilly and Company Limited • NHS Health Technology Assessment Programme
2011	• CRUK • Eli Lilly and Company Limited • AstraZeneca • NHS Health Technology Assessment Programme • MRC
2012	• CRUK • NHS Health Technology Assessment Programme • MRC

2013	• CRUK • NHS Health Technology Assessment Programme • MRC
2014	• CRUK • EORTC • NHS Health Technology Assessment Programme
2015	• CRUK • EORTC • MRC • NHS Health Technology Assessment Programme
2016	• CRUK • MRC • EORTC • NHS Health Technology Assessment Programme
2017	• CRUK • MRC
2018	N/A
2019	N/A
2020	N/A
2021	N/A
2022	N/A
2023	N/A

*** 3.b 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	NSC
Not Sure	

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

N/A - we are not sponsors of studies.

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

N/A - we are not sponsors of studies.

*** 3.e 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)?**

N/A - we are not sponsors of studies.

*** 3.f 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	Not Sure

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

N/A - we are not sponsors of studies. We participate in multi centre studies where funding has already been secured.

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

	Tick one
Yes	
No	No
Unsure	

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

N/A

*** 3.j 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?**

N/A - we are not sponsors of studies. We participate in multi centre studies where funding has already been secured.

*** 3.k 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	Unsure

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

N/A

*** 4. 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	Unsure – staff not in post.
2011	Unsure – staff not in post.
2012	Unsure – staff not in post.
2013	Unsure – staff not in post.
2014	Unsure – staff not in post.
2015	Solid cancer SACT trial opened.
2016	Solid cancer SACT trial running.
2017	Solid cancer SACT trial running.
2018	Changes in infrastructure and collaboration with the local Oncology Cancer Centre.
2019	Changes in infrastructure and collaboration with the local Oncology Cancer Centre.
2020	Changes in infrastructure and collaboration with the local Oncology Cancer Centre. Attempted to open collaboratively, unsuccessful due to trial change.
2021	Changes in infrastructure and collaboration with the local Oncology Cancer Centre. Attempted to open collaboratively, unsuccessful due to trial change.
2022	Changes in infrastructure and collaboration with the local Oncology Cancer Centre.
2023	Changes in infrastructure and collaboration with the local Oncology Cancer Centre.

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

	Tick one
Yes	
No	No
Unsure	

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

N/A

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

	Tick one
Yes	
No	
Unsure	Unsure

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

N/A

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

	Tick one
Yes	Yes
No	
Unsure	

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

Changes in infrastructure and collaboration with the local Oncology Cancer Centre. Attempted to open collaboratively, unsuccessful due to trial change. Limited time to work collaboratively to enable study set up, disrupted by lack of resources inc. staffing.

*** 4.g 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	Unsure

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

N/A

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

Unsure with regards to oncology trials. However, no issue with surgical trials.

*** 4.j 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	Unsure

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

N/A

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

N/A - only participate in multi centre sites that have already been approved.

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

N/A - only participate in multi centre sites that have already been approved.

*** 5. 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	No
Unsure	

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

N/A