Maidstone and Tunbridge Wells NHS Trust

Ref: FOI/GS/ID 8929

**Please reply to:**
FOI Administrator
Trust Management
Maidstone Hospital
Hermitage Lane
Maidstone, Kent
ME16 9QQ
Email: mtw-tr.foiadmin@nhs.net
www.mtw.nhs.uk

21 March 2024

**Freedom of Information Act 2000**

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to Clinical Trials in Oncology.

*You asked: All questions are shown as received by the Trust.*
*Name of person completing out this form:*
*Full name of the hospital or NHS Trust (specify):*
*Your role at the hospital:*
*Your involvement in oncology clinical trials:*
*Is your hospital/ NHS Trust a Cancer Unit, Cancer Centre or Centre of Excellence in Cancer Care?*
*1.Ia What tumour groups do you treat with systemic anti-cancer therapy at your centre?*
*1.Ib Since 2010, for what tumour groups has your organisation had clinical trials involving systemic anti-cancer therapy? Select all that apply.*
*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?*
*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)?*
*1.Ie Of the total number of clinical trials you reported in 1.Ic, how many were PHASE 1 trials?*
*1.If Of the total number of clinical trials you reported in 1.Ic, how many were PHASE 2 trials?*
*1.Ig Of the total number of clinical trials you reported in 1.Ic, how many were PHASE 3 trials?*
*1.Ih On a separate note, how many Phase IV trials did you conduct in each year at your hospital/ Trust?*

*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 trialled systemic anti-cancer therapy within the trial?*
*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:*
*1.Ik In each year, how many new Phase I - III clinical trials did you open for recruitment?*
*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?*
*2.IIIb If yes, please specify the regulatory challenges encountered:*
*2.IVa Have there been any notable changes in the regulatory reporting requirements for ongoing oncology trials post-BREXIT?*
*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?*
*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?*
*2.VIb If yes, please provide examples of the additional documentation or compliance measures introduced:*
*2.VII How has the training and education of clinical trial staff in your centre been impacted by regulatory changes post-BREXIT?*
*2.VIIIa Have there been any changes in the requirements for informed consent processes for oncology trials post-BREXIT?*
*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?*
*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:*
*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:*
*3.III How has the funding landscape for oncology pharmaceutical trials at your centre changed post-BREXIT?*
*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?*
*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?*
*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?*
*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:*
*4.IIa Have there been challenges in maintaining international collaborations for oncology trials post-BREXIT?*
*4.IIb If yes, please identify the main collaborative challenges faced:*
*4.IIIa Have changes in regulatory requirements impacted international partnerships in oncology trials?*
*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?*
*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?*
*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?*
*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?*
*5.Ib If yes, please elaborate on the specific challenges faced and any measures*

Trust response:

| | |
|---|---|
| | Section 40.2 is being applied to this question. Further information can be found on the Trust website using the following link: https://www.mtw.nhs.uk/research |
| **Name of person completing out this form:** | |
| **Full name of the hospital or NHS Trust (specify):** | Maidstone and Tunbridge Wells NHS Trust |
| **Your role at the hospital:** | Research and Innovation Manager |
| **Your involvement in oncology clinical trials:** | Oversee all clinical trials in the trust |

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

| | Tick one |
|---|---|
| Yes | X |
| 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) | X |
| Central nervous system (CNS) | X |
| Skin/ Melanoma | X |
| Urology/ Renal | X |
| Gynae-Onc | X |
| Breast | X |
| Upper Gastrointestinal (UGI) | X |
| Lower Gastrointestinal (LGI) | X |
| Hepato-pancreatico-biliary (HPB) | X |
| Cancer of unknown primary (CUP) Lung | X |
| Sarcoma | X |

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) | X |
| Central nervous system (CNS) | X |
| Skin/ Melanoma | X |
| Urology/ Renal | X |
| Gynae-Onc | X |
| Breast | X |
| Upper Gastrointestinal (UGI) | X |
| Lower Gastrointestinal (LGI) | X |
| Hepato-pancreatico-biliary (HPB) | X |
| Cancer of unknown primary (CUP) Lung | X |
| Sarcoma | X |

| | |
|---|---|
| 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 | 36 |
| 2011 | 37 |
| 2012 | 55 |
| 2013 | 58 |
| 2014 | 56 |
| 2015 | 57 |
| 2016 | 56 |
| 2017 | 53 |
| 2018 | 45 |
| 2019 | 58 |
| 2020 | 51 |
| 2021 | 59 |
| 2022 | 62 |
| 2023 | 57 |

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 | 3 |
| 2011 | 4 |
| 2012 | 4 |
| 2013 | 5 |
| 2014 | 4 |
| 2015 | 4 |
| 2016 | 4 |
| 2017 | 3 |
| 2018 | 3 |
| 2019 | 4 |
| 2020 | 3 |
| 2021 | 1 |
| 2022 | 1 |
| 2023 | 1 |

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 | 1 |
| 2014 | 1 |
| 2015 | 1 |
| 2016 | 1 |
| 2017 | 1 |

| | |
|---|---|
| 2018 | 1 |
| 2019 | 1 |
| 2020 | 0 |
| 2021 | 4 |
| 2022 | 5 |
| 2023 | 7 |

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 | 12 |
| 2011 | 17 |
| 2012 | 23 |
| 2013 | 25 |
| 2014 | 25 |
| 2015 | 22 |
| 2016 | 23 |
| 2017 | 20 |
| 2018 | 17 |
| 2019 | 24 |
| 2020 | 17 |
| 2021 | 17 |
| 2022 | 20 |
| 2023 | 16 |

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 | 24 |
| 2011 | 20 |
| 2012 | 32 |
| 2013 | 32 |
| 2014 | 30 |
| 2015 | 33 |
| 2016 | 32 |
| 2017 | 32 |
| 2018 | 27 |
| 2019 | 33 |
| 2020 | 32 |
| 2021 | 38 |
| 2022 | 37 |
| 2023 | 34 |

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 | 1 |
| 2011 | 2 |
| 2012 | 0 |
| 2013 | 4 |
| 2014 | 3 |
| 2015 | 2 |
| 2016 | 2 |

| | |
|---|---|
| 2017 | 5 |
| 2018 | 5 |
| 2019 | 5 |
| 2020 | 8 |
| 2021 | 10 |
| 2022 | 13 |
| 2023 | 17 |

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 | information not available |
| 2011 | information not available |
| 2012 | information not available |
| 2013 | information not available |
| 2014 | information not available |
| 2015 | information not available |
| 2016 | information not available |
| 2017 | information not available |
| 2018 | information not available |
| 2019 | information not available |
| 2020 | information not available |
| 2021 | information not available |
| 2022 | information not available |
| 2023 | information not available |

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 | 132 |
| 2011 | 208 |
| 2012 | 196 |
| 2013 | 129 |
| 2014 | 91 |
| 2015 | 84 |
| 2016 | 59 |
| 2017 | 66 |
| 2018 | 69 |
| 2019 | 47 |
| 2020 | 27 |
| 2021 | 29 |
| 2022 | 9 |
| 2023 | 5 |

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

| | Number of trials, n |
|---|---|
| 2010 | information not available |
| 2011 | information not available |
| 2012 | information not available |
| 2013 | information not available |

| | |
|---|---|
| 2014 | information not available |
| 2015 | information not available |
| 2016 | information not available |
| 2017 | information not available |
| 2018 | 13 |
| 2019 | 12 |
| 2020 | 8 |
| 2021 | 8 |
| 2022 | 7 |
| 2023 | 2 |

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

Potential impact was whether there would be enough IMP in the country to supply the trial. We found that the trial sponsors envisioned this early on and arrangements were already in place.

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

We have not experienced an impact at our site

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:

Not applicable

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:

Not applicable

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

| | Tick one |
|---|---|
| Yes | X |

| | |
|---|---|
| No | |
| Unsure | |

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

| |
|---|
| Combined review for CTIMPs and combined medicine and device trials, using single application – this has reduced delays in receiving regulatory approvals. |

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

| |
|---|
| Improved timelines by single applications |

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

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

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

| |
|---|
| Mainly for sponsors of CTIMPS, not sites hosting trials. |

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

| |
|---|
| NIHR training has included post-BREXIT changes delivered regularly to NHS trusts |

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:

| |
|---|
| Not applicable |

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

| |
|---|
| Registration of trials, publishing reviews, future requirements |

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

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

2.Xb If yes, explain how:

| |
|---|
| Staff meetings, staff training (internal and external (NIHR)) |

2.Xc If no, explain why not:

| |
|---|
| Not applicable |

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 | information not available |
| 2011 | information not available |
| 2012 | information not available |
| 2013 | information not available |
| 2014 | information not available |
| 2015 | information not available |
| 2016 | information not available |
| 2017 | information not available |
| 2018 | information not available |
| 2019 | information not available |
| 2020 | information not available |
| 2021 | information not available |
| 2022 | information not available |
| 2023 | information not available |

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 | Amgen Inc.<br>AstraZeneca UK Limited<br>Breakthrough Breast Cancer<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>Eli Lilly and Company Limited<br>European Organisation for Research and Treatment of Cancer<br>F. Hoffmann-La Roche Ltd<br>FORUM PHARMACEUTICALS INC.<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Medical Research Council (MRC)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>ORCHID CANCER APPEAL<br>SCHERING-PLOUGH LIMITED |
| 2011 | Amgen Inc.<br>Astellas Pharma Europe BV |

| | |
|---|---|
| | AstraZeneca UK Limited<br>Breakthrough Breast Cancer<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>Eisai Co.,Ltd.<br>Eli Lilly and Company Limited<br>European Organisation for Research and Treatment of Cancer;<br>F. Hoffmann-La Roche Ltd<br>FORUM PHARMACEUTICALS INC.<br>Genentech, Inc<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Medical Research Council (MRC)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Otsuka Pharmaceutical Co.,Ltd.<br>SANOFI<br>SCHERING-PLOUGH LIMITED |
| 2012 | Astellas Pharma Europe BV<br>AstraZeneca UK Limited<br>AVENTIS PHARMA LIMITED<br>Boehringer Ingelheim Ltd<br>Breakthrough Breast Cancer<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>Cancer Research UK<br>Eisai Co.,Ltd.<br>Eli Lilly and Company Limited<br>Endocyte<br>European Organisation for Research and Treatment of Cancer<br>EXELIXIS STEM CELL SCIENCES, INC.<br>F. Hoffmann-La Roche Ltd<br>Genentech, Inc<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Medical Research Council (MRC)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>ORCHID CANCER APPEAL<br>Otsuka Pharmaceutical Co.,Ltd.<br>Pfizer Inc.<br>SANOFI<br>SCHERING-PLOUGH LIMITED |
| 2013 | ABRAXIS BIOSCIENCE LIMITED<br>Amgen Inc.<br>Astellas Pharma Europe BV<br>AstraZeneca UK Limited<br>AVENTIS PHARMA LIMITED<br>Boehringer Ingelheim Ltd<br>Breakthrough Breast Cancer<br>Cancer Research UK<br>Eli Lilly and Company Limited<br>Endocyte<br>European Organisation for Research and Treatment of Cancer<br>EXELIXIS STEM CELL SCIENCES, INC.<br>F. Hoffmann-La Roche Ltd<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Medical Research Council (MRC) |

| | |
|---|---|
| | MedImmune, LLC<br>MERCK SERONO LIMITED<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>ORCHID CANCER APPEAL<br>Pfizer Inc.<br>SCHERING-PLOUGH LIMITED<br>Tesaro Inc<br>Verastem, Inc |
| 2014 | AB SCIEX UK LIMITED<br>ABBVIE INC.<br>ABRAXIS BIOSCIENCE LIMITED<br>Amgen Inc.<br>Aragon Pharmaceuticals<br>AstraZeneca UK Limited<br>AVENTIS PHARMA LIMITED<br>Boehringer Ingelheim Ltd<br>Cancer Research UK<br>European Organisation for Research and Treatment of Cancer<br>F. Hoffmann-La Roche Ltd<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>MedImmune, LLC<br>MERCK SERONO LIMITED<br>MERCK SHARP & DOHME CORP.<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>ORCHID CANCER APPEAL<br>ORION PHARMA (UK) LIMITED<br>Pfizer Inc.<br>Pfizer Inc.<br>SCHERING-PLOUGH LIMITED<br>SOTIO a.s.<br>Tesaro Inc<br>Verastem, Inc |
| 2015 | AB SCIEX UK LIMITED<br>ABBVIE INC.<br>ABRAXIS BIOSCIENCE LIMITED<br>Amgen Inc.<br>Aragon Pharmaceuticals<br>AstraZeneca UK Limited<br>AVENTIS PHARMA LIMITED<br>Boehringer Ingelheim Ltd<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>Eli Lilly and Company Limited<br>European Organisation for Research and Treatment of Cancer<br>F. Hoffmann-La Roche Ltd<br>Genentech, Inc<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>MacroGenics, Inc.<br>MedImmune, LLC; MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>MERCK SHARP & DOHME CORP.<br>MERCK SHARP & DOHME CORP.<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED |

| | |
|---|---|
| | Morphotek Inc.<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUCANA PLC<br>ORION PHARMA (UK) LIMITED<br>Pfizer Inc.<br>SCHERING-PLOUGH LIMITED<br>SOTIO a.s.<br>Tesaro Inc<br>Verastem, Inc |
| 2016 | AB SCIEX UK LIMITED<br>ABRAXIS BIOSCIENCE LIMITED<br>Aragon Pharmaceuticals<br>ARIAD Pharmaceuticals, Inc.<br>AstraZeneca UK Limited<br>Boehringer Ingelheim Ltd<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>European Organisation for Research and Treatment of Cancer<br>EXELIXIS STEM CELL SCIENCES, INC.<br>F. Hoffmann-La Roche Ltd<br>Genentech, Inc<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>MacroGenics, Inc.<br>MedImmune, LLC; MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>MERCK SHARP & DOHME CORP.<br>Morphotek Inc.<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUCANA PLC<br>ORION PHARMA (UK) LIMITED<br>Pfizer Inc.<br>SERVIER LABORATORIES<br>SOTIO a.s. |
| 2017 | ABBVIE INC.<br>AIO-Studien-gGmbH<br>ARIAD Pharmaceuticals, Inc.<br>AstraZeneca UK Limited<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>EXELIXIS STEM CELL SCIENCES, INC.<br>Eisai Co.,Ltd.<br>European Commission<br>European Organisation for Research and Treatment of Cancer<br>F. Hoffmann-La Roche Ltd<br>June Hancock Mesothelioma Research Fund<br>MacroGenics, Inc.<br>MedImmune, LLC<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>MERCK SHARP & DOHME CORP.<br>NIHR Central Commissioning Facility (CCF)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUCANA PLC<br>ORION PHARMA (UK) LIMITED |

| | |
|---|---|
| | Pfizer Inc.<br>SOTIO a.s.<br>Stiftung European Thoracic Oncology Platform |
| 2018 | ABBVIE INC.<br>AIO-Studien-gGmbH<br>AstraZeneca UK Limited<br>Bayer Pharma AG<br>Boehringer Ingelheim Ltd<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>Eisai Co.,Ltd.<br>European Commission<br>European Organisation for Research and Treatment of Cancer<br>EXELIXIS STEM CELL SCIENCES, INC.<br>INCYTE PHARMA UK LTD<br>Kidney Cancer Care Ltd (Kidney Cancer UK)<br>MacroGenics, Inc.<br>MedImmune, LLC<br>Merck & Co Inc<br>MERCK SHARP & DOHME CORP.<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>NIHR Central Commissioning Facility (CCF)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUCANA PLC<br>Pfizer Inc.<br>SERVIER LABORATORIES<br>Stiftung European Thoracic Oncology Platform |
| 2019 | ABBVIE INC.<br>ACCURAY UK, LTD.<br>AstraZeneca UK Limited<br>BEIGENE USA, INC.<br>Boehringer Ingelheim Ltd<br>Bristol-Myers Squibb International Corporation<br>Cancer Research UK<br>Eisai Co.,Ltd.<br>European Commission<br>European Organisation for Research and Treatment of Cancer<br>EXELIXIS STEM CELL SCIENCES, INC.<br>F. Hoffmann-La Roche Ltd<br>INCYTE PHARMA UK LTD<br>June Hancock Mesothelioma Research Fund<br>Kidney Cancer Care Ltd (Kidney Cancer UK)<br>MacroGenics, Inc.<br>MedImmune, LLC<br>Merck & Co Inc<br>MERCK SHARP & DOHME CORP.<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>NIHR Central Commissioning Facility (CCF)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUCANA PLC<br>PELICAN CANCER FOUNDATION<br>Pfizer Inc.<br>SERVIER LABORATORIES |

| | |
|---|---|
| 2020 | ABBVIE INC.<br>AstraZeneca UK Limited<br>BEIGENE USA, INC.<br>Boehringer Ingelheim Ltd<br>Bristol-Myers Squibb International Corporation<br>Canadian Cancer Trials Group<br>Cancer Research UK<br>Eli Lilly and Company Limited<br>EXELIXIS STEM CELL SCIENCES, INC.<br>F. Hoffmann-La Roche Ltd<br>Hinova Pharmaceuticals Inc.<br>INCYTE PHARMA UK LTD<br>Ipsen Innovation<br>Kidney Cancer Care Ltd (Kidney Cancer UK)<br>MedImmune, LLC; MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>Merck & Co Inc<br>MERCK SHARP & DOHME CORP.<br>NIHR Central Commissioning Facility (CCF)<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUCANA PLC<br>Pfizer Inc.<br>SANOFI<br>SEAGEN U.K. LTD.<br>SERVIER LABORATORIES |
| 2021 | ABBVIE INC.<br>Allarity Therapeutics A/S<br>ARCUS BIOSCIENCES, INC.<br>AstraZeneca UK Limited<br>Bristol-Myers Squibb International Corporation<br>Canadian Cancer Trials Group<br>Cancer Research UK<br>DAIICHI SANKYO COMPANY LIMITED<br>Eli Lilly and Company Limited<br>European Commission<br>F. Hoffmann-La Roche Ltd<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Hinova Pharmaceuticals Inc.<br>INCYTE PHARMA UK LTD<br>INVITAE CORPORATION; Pfizer Inc.<br>Ipsen Innovation<br>Kidney Cancer Care Ltd (Kidney Cancer UK)<br>MedImmune, LLC<br>Merck & Co Inc<br>MERCK SHARP & DOHME CORP.<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>NUCANA PLC<br>NUVECTIS PHARMA, INC.<br>Pfizer Inc.<br>SANOFI<br>SEAGEN U.K. LTD.<br>TAIHO ONCOLOGY INC<br>Tavanta Therapeutics Hungary Zrt. |

| | |
|---|---|
| 2022 | ABBVIE INC.<br>ADVENCHEN LABORATORIES, LLC<br>Allarity Therapeutics A/S<br>Amgen Inc.<br>ARCUS BIOSCIENCES, INC.<br>AstraZeneca UK Limited<br>BioNTech SE<br>Bristol-Myers Squibb International Corporation<br>Canadian Cancer Trials Group<br>Cancer Research UK<br>DAIICHI SANKYO COMPANY LIMITED<br>Eli Lilly and Company Limited<br>F. Hoffmann-La Roche Ltd<br>Gilead Sciences Inc<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Hinova Pharmaceuticals Inc.<br>INCYTE PHARMA UK LTD<br>INVITAE CORPORATION; Pfizer Inc.<br>Kidney Cancer Care Ltd (Kidney Cancer UK)<br>MedImmune, LLC<br>Merck & Co Inc<br>MERRIMACK PHARMACEUTICALS U.K. LIMITED<br>MIRATI THERAPEUTICS, INC.<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>NUVECTIS PHARMA, INC.<br>Pfizer Inc.<br>REVOLUTION MEDICINES, INC.<br>RIBON THERAPEUTICS, INC.<br>TAIHO ONCOLOGY INC<br>Tavanta Therapeutics Hungary Zrt. |
| 2023 | ABBVIE INC.<br>ADVENCHEN LABORATORIES, LLC<br>Allarity Therapeutics A/S<br>AstraZeneca UK Limited<br>Bayer Pharma AG<br>BioNTech SE<br>Cancer Research UK<br>CARRICK THERAPEUTICS UK LIMITED<br>DAIICHI SANKYO COMPANY LIMITED<br>Eli Lilly and Company Limited<br>ELLIPSES PHARMA LTD<br>F. Hoffmann-La Roche Ltd<br>Fore Biotherapeutics<br>Genentech, Inc<br>Gilead Sciences Inc<br>GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED<br>Hinova Pharmaceuticals Inc.<br>INCYTE PHARMA UK LTD<br>INVITAE CORPORATION; Pfizer Inc.<br>Kidney Cancer Care Ltd (Kidney Cancer UK)<br>Merck & Co Inc<br>MIRATI THERAPEUTICS, INC.<br>NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)<br>Novartis Pharma AG<br>Novartis Pharma AG |

| | |
|---|---|
| | NUVECTIS PHARMA, INC.<br>Pfizer Inc.<br>RIBON THERAPEUTICS, INC. |

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 | X |
| Not Sure | |

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

Not applicable

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

Not applicable

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)?

No significant changes

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?

Specific trust policy changes not required. Mainly charitable, non-commercial funding organisations may have required specific policy changes.

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

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

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

Utilising databases/resources such as ResearchConnect, TrinetX

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?

| |
|---|
| Promotion of Patient Research Ambassadors, growing patient focus groups across organisation. PRES survey feedback. |

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 | X |
| Unsure | |

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

| |
|---|
| Not applicable |

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 aware of any |
| 2011 | not aware of any |
| 2012 | not aware of any |
| 2013 | not aware of any |
| 2014 | not aware of any |
| 2015 | not aware of any |
| 2016 | not aware of any |
| 2017 | not aware of any |
| 2018 | not aware of any |
| 2019 | not aware of any |
| 2020 | not aware of any |
| 2021 | not aware of any |
| 2022 | not aware of any |
| 2023 | not aware of any |

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:

| |
|---|
| Not applicable |

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:

| |
|---|
| Not applicable |

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

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

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

| |
|---|
| Not applicable |

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 | X |
| Unsure | |

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

| |
|---|
| Not applicable |

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

| |
|---|
| Additional International Data Transfer Agreements, National Contract templates (HRA) updated and used across NHS sites. |

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 | X |
| Unsure | |

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

| |
|---|
| Not applicable |

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

| |
|---|
| We have not experienced an effect 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?

| |
|---|
| Strategies/initiatives for research are led by NIHR, HRA, MHRA bodies. |

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 | X |
| Unsure | |

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

| |
|---|
| Not applicable |