

Commercial Research Delivery Finance and Performance Framework

1. Purpose

The purpose of this framework is to outline the required ways of working for ensuring financial transparency, performance monitoring and achieving sustainability in relation to the delivery of commercial clinical research in Wales.

The implementation of this framework will be piloted on the Voluntary Scheme for Branded Medicines Pricing and Access (VPAG) funding and programme of work with the aim to evolve and apply to the wider delivery of commercial research in Wales.

Adherence to this framework is part of the terms and conditions of the VPAG grant award letter issued by Welsh Government.

This framework is being evaluated in use and therefore updates will be issued as the process is refined. The most current version is published on the [Health and Care Research Wales website](#).

2. Scope of framework

This framework is relevant to all those involved in the delivery of commercial clinical research across Wales. The implementation of this framework is being piloted initially with all NHS organisations in receipt of VPAG Funding.

3. Background

Clinical commercial research is a vital part of a vibrant UK life sciences sector. It is well understood by ministers and their respective governments, patients, service users, and others that commercial research improves the health and wealth of the nation and hence there has been a growing awareness and demand for research-driven solutions leading to both patient/public benefit as well as creating economic benefits.

The increasing interest in commercial research, particularly within health and care, is driven by its potential to improve both the health and wealth of the nation – from various stakeholders, including ministers, patients, service users, and others. This indicates

The Association of the British Pharmaceutical Industry (ABPI) reported a 44% decline between 2017 and 2022 in the number of industry clinical trials initiated in the UK, impacting patient access to innovative treatments and the UK's global standing in pharmaceutical research (ABPI 2022). To

improve the UK's global market position, the 2024 Voluntary Scheme for Branded Medicines Pricing and Access (VPAG), a non-contractual agreement negotiated between DHSC (on behalf of the four nations), NHS England and the ABPI, have invested £300 million in the UK to bolster the NHS's capacity to deliver commercial clinical research available across all four nations. Wales is receiving £22.1M between 2024-2029.

4. Once for Wales initiatives

To achieve the ambition of making Wales an attractive place to conduct commercial clinical research within a UK (and global context), collaboration across the Wales commercial research infrastructure is key. In Wales, existing commercial research delivery capability has been networked to create a 'collective' across NHS Wales supported by the national research delivery team. This is known as Commercial Research Delivery Wales (CRDW). The CRDW is also part of a UK wide commercial infrastructure with expectations that Wales also meets the UK requirements.

To further facilitate a One Wales commercial research infrastructure, NHS organisations are expected to engage in national activities led by Health and Care Research Wales on national projects that drive improvements related to commercial research delivery.

NHS organisations receiving VPAG funding are required, through the Terms & Conditions in receipt of this funding, to engage with and adopt One Wales approaches to research delivery where applicable, working with the national research delivery team. This includes, for example:

- All studies where there are multiple sites open in Wales
- One site Wales studies i.e. where a single site covers multiple recruiting locations/ or hub-spoke models of delivery
- Studies that are sponsored by companies where there is a commercial strategic partnership in place e.g. Moderna, BioNTech
- Other high priority studies as directed by Welsh Government.

5. VPAG governance arrangements

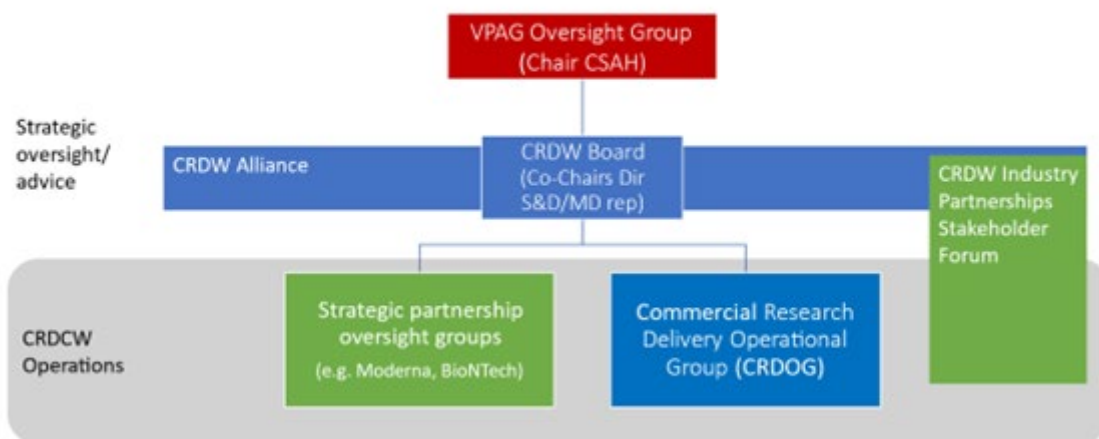
The Chief Pharmaceutical Officer (CPO) for Wales is the Senior Responsible Officer (SRO) for VPAG. A Welsh Government VPAG Oversight Group is in place to provide assurance that the VPAG clinical trials programme specifically is being delivered in accordance with the terms of the

ABPI agreement. The CPO reports to the UK VPAG Investment Board on compliance with the terms of the agreement.

Deployment and oversight of the VPAG clinical trials programme and related investment plan in Wales is delegated to the National Director of Research Support and Delivery, Health and Care Research Wales who reports to the Chief Scientific Advisor for Health in Welsh Government and the Welsh Government VPAG Oversight Group.

The CRDW Board is the decision-making group related to the VPAG Investment Programme and wider service improvement programme related to commercial research delivery. It is co-chaired by the National Director of Research Support & Delivery (programme lead) and an NHS Organisation Medical Director representative.

The CRDW Board is informed by a stakeholder CRDW Alliance (broad membership from across Wales's commercial research delivery stakeholders/infrastructure) and various industry forums (Wales wide, specialty specific and UK).



6. Financial Responsibility and Transparency

The [NHS R&D finance policy](#) covers the details and mechanisms necessary for the management, accountability and distribution of any NHS research funding and income in each NHS organisation in Wales. In line with the requirement set out in the Welsh Health Circular (WHC/2018/005) and subsequent Welsh Health Circulars, all NHS R&D organisations must manage research income as outlined in the most recent NHS R&D finance policy.

6.1 Management and reporting of VPAG Funding

VPAG funding will be issued under a Welsh Government Grant Award Letter (GAL) which will outline the specific funding and its purpose and use. As per the NHS R&D finance policy, VPAG funding must be managed via ring-fenced research accounts on each NHS organisation's central ledger, subject to the usual accounting rules and NHS financial standing orders.

The NHS organisation and named leads are responsible for maximising the use of the VPAG funding alongside other funding streams, such as commercial income, to invest in the growth of capacity and capability for commercial research within their organisation and across Wales.

The named lead(s) (as named in the GAL) is expected to ensure that this is agreed, reported and overseen through local organisation governance structures. The named lead(s) have full responsibility for the oversight and submission of spending plans to the national research funding team. It is expected that the named lead(s) within the NHS organisation nominates operational contacts at a minimum a research delivery lead and a named R&D finance lead.

Each named lead is required to submit a monthly financial report, the purpose of which is to:

- Report on how VPAG funding has been spent in the previous month (actual expenditure compared to planned) to enable the national funding team to monitor and report use
- Identify changes to the spending plan that impact on the forecast spend, and require review and action
- The VPAG GAL holder and/or nominated operational contacts are required to meet with the national funding team monthly to review the plan
- Identify any risks in relation to spend.

The named lead(s) is expected to ensure that this is agreed, reported and overseen through NHS organisation governance structures.

Dates for submission can be found in the VPAG spending plan guidance (Appendix one)

6.2 Management and reporting of commercial income

Commercial research delivery generates income for increasing and sustaining capacity and capability within research in the NHS (capacity building element of the contract), in addition to delivering cost savings by funding trial drugs and participant care.

To maximise these benefits, NHS organisations should have visibility of their research delivery and income.

Each NHS organisation is required to submit a quarterly financial report on the amount of commercial income received by the NHS organisation in the previous quarter. In relation to the VPAG funding investment, the purpose of the reporting is to:

- Demonstrate the amount of commercial income against the sustainability plan (see section 7) and return on investment
- Monitor the use of commercial income in line with the NHS R&D finance policy
- Report commercial capacity building income generated from the set up and delivery of commercial research and demonstrate reinvestment in sustaining and growing capacity within R&D
- Identify any risks in relation to forecasted cost recovery.

7. Capacity building and sustainability

The capacity building element in commercial contract research costings is intended to support a sustainable research infrastructure in the NHS to support research capability and capacity.

Organisational and national-level visibility of commercial research income and how it is utilised is required to demonstrate this sustainability.

The NHS Organisation is expected to develop a capacity building investment plan to allow for commercial income to move where needed within the organisation, including between departments and specialties, to ensure sustainability and grow capacity across the commercial portfolio in a range of services.

Growing and sustaining capacity and capability nationally is also key in the ambition of Wales being a competitive location to conduct commercial research in a global market. The ability to move commercial income and funding across the commercial research infrastructure is vital. The national funding team will continue to scope and establish a model to allow for commercial income and funding to move across Wales which may include linking with other sources of funding (such

as research delivery funding) to support Wales-wide sustainability and maintain capacity for national oversight and initiatives.

8. Adhering to National Mandates

8.1 National Contract Value Review

NHS organisations are required to fully adhere to the National Contract Value Review (NCVR) process to speed up the costing and contracting activities for commercially sponsored research studies. This UK-wide approach is mandatory for commercial companies delivering all phases of clinical trials in NHS organisations. NHS organisations are required to accept the single study resource review outcome and the local price generated by the interactive Costing Tool (iCT) for all commercial studies as part of NCVR. **Sites must not apply their own NHS organisation's prices for commercially contract research.** Where sites have concerns regarding the lead site costings, the correct escalation process must be followed as outlined in the NCVR Escalation Pathway - [Infogram](#).

8.2 Commercial agreements

NHS Organisations are required to use all [UK-agreed template agreements without modification](#). This includes but is not limited to:

- [Model Clinical Trial Agreement \(mCTA\) and CRO-mCTA](#)
- [Commercial Model Clinical Trial Agreements for Investigational Advanced Therapy Medicinal Products \(ATMP-mCTA and CRO-ATMP-mCTA\)](#)
- [Commercial Primary Care Model Clinical Trial Agreement \(PC-mCTA\)](#)
- [model Clinical Investigation Agreement \(mCIA\) and CRO-mCIA](#)
- [model Non-Interventional Study Agreement \(mNISA\) and Clinical Research Organisation mNISA \(CRO-mNISA\)](#)
- [UK template Hub and Spoke Agreements](#)
- Model Commercial Participant Identification Centres Agreement (mC-PICA)
- [Model Material Transfer Agreement](#)
- Model Confidentiality Disclosure Agreements (mCDA)
- [Model Commercial Chief Investigator Agreement \(mCCIA\) and clinical research organisation mCCIA \(CRO-mCCIA\)](#)
- [Other model commercial agreements](#) as/when published in the link above

9. Responding to commercial sponsor enquiries

Communication with sponsors is key to successful partnerships and prompt responses from NHS organisations in relation to the following areas is expected:

9.1 UK wide Site Identification

NHS organisations will be expected to work closely with the national research delivery team, Wales specialty leads and with commercial sponsors/CROs to identify and assess potential research locations and One Wales opportunities. Organisations are expected to adhere to feasibility deadlines.

9.2 Study setup queries from sponsors

NHS organisations are expected to respond promptly to sponsor queries related to study setup progress. Queries often cover a range of topics from contract and costing reviews, outstanding study documentation, training or other aspects of setup such as arrangement of support services, regardless of the nature, queries should be acknowledged by the site representative within 48 hours of receiving them. When resolution of queries is expected to take longer than 48 hours, regular progress updates (at a frequency agreed with the sponsor and/or the national research delivery team) should be given to maintain good working relationships and reduce sponsor anxiety around setup times.

9.3 Performance queries from sponsors

Queries related to underperforming studies should be acknowledged by the site representative within 48 hours of receiving them. When resolution of queries is expected to take longer than 48 hours, regular progress updates (at a frequency agreed with the sponsor and/or Health and Care Research Wales) should be given to maintain good working relationships and reduce sponsor anxiety around performance. NHS organisations are expected to be receptive to discussions around mitigating risks in relation to performance. Both queries direct from sponsors and those escalated through the national research delivery team should be addressed as priority by the appropriate NHS organisation operational lead.

10. Performance Management of VPAG funding

On receipt of VPAG funding, baseline data on commercial income and performance data linked to each applicant's SMART objectives will be obtained from each named lead(s) within the VPAG GAL issued by Welsh Government.

NHS organisations are required to fully comply with the Terms and Conditions as stated in the VPAG GAL issued by Welsh Government.

As a minimum, NHS organisations in receipt of VPAG funding are expected to:

- Ensure achievement of commercial research delivery metrics associated with agreed Key Performance Indicators (UK and Wales)
- Re-invest commercial income (direct cost recovery, surplus and capacity building funding) into research infrastructure.
- Fully comply with NCVR
- Use unmodified model agreements for contracting.
- Report against SMART objectives

10.1 Quarterly performance monitoring meetings (VPAG)

The named lead(s) and nominated operational leads in receipt of VPAG funding are required to attend a quarterly performance monitoring meeting with the national research delivery team. The purpose of this is to discuss:

- Progress against SMART objectives
- Progress against relevant Wales and CRDC UK performance metrics
- Alignment with national mandates
- Risks associated with performance

Details on finance and performance outcomes will be shared with the VPAG oversight group.

Appendix two provides a summary table outlining the reporting and meeting requirements associated with this framework.

11. Monitoring and review of this guidance

This framework is evaluated in use and as processes are further defined, this guidance will be updated as required. To provide feedback in relation to this, please contact research-fundingsupport@wales.nhs.uk.

Appendix one – VPAG Spending Plan Guidance

Commercial Research Delivery Wales Funding (VPAG)

Spending Plan Guidance

1. Purpose

The purpose of this guidance is to provide the named lead(s) in the VPAG Grant Award Letters (GAL) and NHS organisations in receipt of VPAG funding with the technical description of the VPAG funding spending plans and the required reporting process to be followed. This includes:

- Describing the financial reporting process.
- A detailed description of the format of the spending plans.

2. Receiving VPAG Funding

Named lead(s) and NHS organisations will receive a GAL from Welsh Government, highlighting the amount of VPAG funding they will be receiving in total and within each financial year, profiled quarter one to quarter four. The amount of funding to be received from Welsh Government will be clearly defined within the summary sheet of the spending plan and is the accurate representation of the funding the named lead(s) and NHS organisation can expect to receive per financial quarter, unless there are changes agreed in-year. Any changes to VPAG funding will be ratified through a variation to contract at quarter four.

3. Managing VPAG funding and monthly financial reports

The VPAG spending plans/returns should be used by the named lead(s)/NHS organisations as the local day-to-day financial management tool for recording VPAG income and expenditure, allowing for straightforward monthly financial status reports to be submitted to the national research funding team.

The VPAG spending plan template consists of up to seven worksheets:

- **VPAG Award Summary:** Four-year funding summary
- **2025/26 Summary:** 2025/26 quarterly and monthly funding and expenditure summary
- **2025/26 Detail:** 2025/26 monthly breakdown of expenditure, by individual post/non-staff cost
- **2026/27:** Quarterly breakdown of 2026/27 forecast, by post/non-staff cost
- **2027/28:** Quarterly breakdown of 2027/28 forecast, by post/non-staff cost
- **2028/29:** Quarterly breakdown of 2028/29 forecast, by post/non-staff cost
- **Spending Plan:** Annual breakdown of four-year spending plan, by post/non-staff cost

More detailed information regarding each worksheet and what is recorded in each column can be found in sub-appendix 1. Submission dates for the monthly financial reports can be found in sub-appendix 2.

4. Managing commercial trial income

VPAG spending plans rely on cost recovery from commercial trial income to balance expenditure against the funding awarded.

All forecasted commercial cost recovery must be profiled as forecasted throughout the financial year via the monthly return process. Any reduction or loss of commercial income against the original agreed spending plan must be met by the NHS organisation unless there is prior agreement to increase the VPAG funding to the organisation.

The named lead(s) and NHS organisations are required to provide a quarterly breakdown of their commercial income, by study, using the commercial income sheet (as per the Terms & Conditions within the GAL), so that the context in which the VPAG funding is being utilised and income generated and reinvested in research infrastructure is visible.

5. Forecasting for 2026/27 – 2028/29

The 2026/27 – 2028/29 forecast is based on the figures agreed with the national research funding team when spending plans and grant award values were confirmed. NHS organisations are encouraged to track the impact of and agreed changes in 2025/26 on the 2026/27 – 2028/29 forecast to ensure the full year impact of any changes is clear.

6. Monthly finance review meetings

The national research funding team will hold monthly finance review meetings with NHS organisations' R&D delivery leads, R&D managers and R&D finance leads and the VPAG funding financial position(s) will be part of the discussions. When needed, the named lead(s) may be invited to attend to discuss any queries in relation to a specific application.

Sub-appendix one - Spending plan worksheets

VPAG Award Summary worksheet

This worksheet summarises all the financial information across four years, including overall funding granted which is split over four financial years as per the application, all the columns are self-populating.

2025/26 Summary worksheet

This worksheet summarises all the financial information within the 2025/26 Monthly spreadsheet and all the columns are self-populating.

A monthly and quarterly summary is provided to capture the initial agreed 2025/26 VPAG funding award/expenditure profile and revised forecast expenditure. At the beginning of the financial year, the monthly breakdown is shown as equal twelfths of the annual total. Prior to submission of the quarter 1 financial status report, this should be updated to reflect a more accurate forecast of all costs by amending the monthly forecast and actual expenditure against each post in the 2025/26 Monthly worksheet. At the bottom of this worksheet, there is an amount to cover the increase in National Insurance and pay award for 2025/26. This has been provided as an estimation based on the initially agreed forecast and should also be updated each month to reflect the most accurate position.

The annual total of the initial agreed VPAG funded costs is shown in cell D9. Any deviations from this plan on a monthly basis throughout the year will be reflected in the monthly totals and will update the revised forecast, shown in cell Q9.

The amount shown in cell D9 will form the basis of the VPAG Grant Award Letter from Welsh Government. Funding will be administered to NHS organisations by Welsh Government quarterly

in arrears, after the final monthly spending plans have been signed off, based on the quarterly totals reported in row 10.

When making amendments to the costs reported within each worksheet throughout the year, any resulting variance from the initial spending plan will be displayed in column R.

2025/26 Monthly worksheet

This worksheet displays planned VPAG expenditure when the initial spending plans were agreed, with the addition of further columns to display the following information against each row of expenditure:

- **Monthly breakdown of Gross Expenditure**
For each row of expenditure, the annual total has been divided into equal twelfths for reporting the monthly gross expenditure forecast (before cost recovery), unless confirmed otherwise. If necessary, please amend the monthly breakdown to report a more accurate profile.
- **Monthly breakdown of Cost Recovery**
NHS organisations should enter the full amount (£) of monthly actual/forecast costs recovered against a specific post from a commercial (or other) income source. Please provide details of the source and an explanation of any changes throughout the year, using the comments column.
- **Monthly breakdown of Net Expenditure**
For each row of expenditure, the annual total has been divided into equal twelfths for reporting the monthly net expenditure forecast (after cost recovery), unless confirmed otherwise. These columns automatically calculate monthly net expenditure based on the figures populated in the monthly gross expenditure and cost recovery columns. Please do not delete the contents of these columns as the formulae will not work.
- **Revised Forecast Gross Expenditure**
This column **automatically calculates** the full year gross costs (before cost recovery) based on the figures entered in the monthly expenditure/forecast columns. Please do not delete the contents of this column as the formulae will not work.
- **Revised Forecast Cost Recovery**
This column **automatically calculates** the full year forecast cost recovery based on the figures entered in the monthly actual/forecast cost recovery columns. If the contents of this column are deleted the formulae will not work.
- **Revised Forecast Net Expenditure**
This column **automatically calculates** the full year funding required based on the figures entered in the monthly expenditure/forecast columns. Please do not delete the contents of this column as the formulae will not work.
- **Variance (from initial Spending Plan)**
This column **automatically calculates** the variance of the revised full year forecast, compared to the initial Spending Plan. Please do not delete the contents of this column as the formulae will not work.
Please note that a positive figure **depicts an overspend** and a negative figure **depicts an underspend**. NHS organisations should use the comments column to explain variances, see guidance below.
- **Comments**
Where there is a variance from the original spending plan (over or underspend), **NHS organisations should provide comments** to explain the reasons against each relevant line.

Detailed worksheet breakdown:

- **Column A: Post Title:** The post title or a brief description of the resource.
- **Column B: Band:** If the resource relate to a specific post, please enter the banding of this post, using the NHS Agenda for Change banding. If a banding from a different pay scale applies, please specify.
- **Column C: WTE (if applicable):** if the resources relates to a specific post, the Whole Time Equivalent is entered in this column.

Please note that WTE refers to the recurring weekly hours worked by a member of staff, so should not be used for one off payments (these can be included, but no WTE is required – the comments column can be used to confirm that no WTE is applicable).

- **Column D: Forecast Gross Expenditure 2025/26:** The forecasted cost of each resource, between 01 April 2025 and 31 March 2026.
- **Column E: Forecast cost recovery 2025/26:** The forecasted amount that will be recovered against the post/ cost listed.
- **Column F: Forecast Net Expenditure:** Column auto-populates the net expenditure to be funded by VPAG, deducting cost recovery, if applicable.
- **Columns G-AP:** Twelve-month breakdown of Actual/Forecast Gross Expenditure, Cost Recovery and net expenditure.
- **Coumns AQ-AY:** Revised 2025/26 full-year forecast Agreed Gross Expenditure, Revised Gross Expenditure, Gross Variance, Agreed Cost Recovery, Revised Cost Recovery, Cost Recovery Variance, Agreed Net Expenditure, Revised Net Expenditure, Net Variance (from agreed spending plan).
- **Column AU: Comments:** Information that will provide more detail against each entry as required.

2026/27-2028/29 Worksheets

These worksheets display the annual planned VPAG expenditure when the initial spending plans were agreed, with the addition of further columns to display the following information against each row of expenditure:

- **Quarterly breakdown of Gross Expenditure**
For each row of expenditure, the annual total has been divided into equal quarterly amounts, showing the quarterly gross expenditure forecast (before cost recovery), unless confirmed otherwise. If necessary, please amend the quarterly breakdown to report a more accurate profile.
- **Quarterly breakdown of Cost Recovery**
NHS organisations should enter the full amount (£) of quarterly forecast costs to be recovered against a specific post from a commercial (or other) income source.
- **Quarterly breakdown of Net Expenditure**
For each row of expenditure, the annual total has been divided into equal quarterly amounts showing the quarterly net expenditure forecast (after cost recovery), unless confirmed otherwise. These columns automatically calculate quarterly net expenditure based on the figures populated in the quarterly gross expenditure and cost recovery columns. Please do not delete the contents of these columns as the formulae will not work.
- **Revised Forecast Gross Expenditure**

This column **automatically calculates** the full year gross costs (before cost recovery) based on the figures entered in the quarterly expenditure/forecast columns. Please do not delete the contents of this column as the formulae will not work.

- **Revised Forecast Cost Recovery**

This column **automatically calculates** the full year forecast cost recovery based on the figures entered in the quarterly actual/forecast cost recovery columns. Please do not delete the contents of this column as the formulae will not work.

- **Revised Forecast Net Expenditure**

This column **automatically calculates** the full year funding required based on the figures entered in the quarterly expenditure/forecast columns. Please do not delete the contents of this column as the formulae will not work.

Spending Plan worksheet

This worksheet displays the detailed breakdown of the agreed four-year planned VPAG expenditure by post/non-staff cost, as submitted with the VPAG funding application and revised through further discussion with Health and Care Research Wales.

NHS organisations are not required to make changes to this sheet during 2025/26, unless discussed with the Health and Care Research Wales funding team and agreed changes within the individual financial year worksheets are required.

Sub-appendix 2: Monthly Spending Plan return submission dates 2025/26

Monthly spending plans must be submitted by the deadlines outlined below, with up-to-date actual and forecast expenditure. Quarterly actual and forecast commercial income by study must be updated at each of the quarterly submission deadlines.

Reporting Period	Submission Deadline
July 2025 (Quarter 1)	18 August 2025
August 2025	16 September 2025
September 2025 (Quarter 2)	16 October 2025
October 2025	18 November 2025
November 2025	16 December 2025
December 2025 (Quarter 3)	19 January 2026
January 2026	17 February 2026
February 2026	17 March 2026
March 2026 (Quarter 4)	16 April 2026

Support available

The national research funding team are available to support organisations to answer queries, and can also help make changes to the spending plan if required - Research-FundingSupport@wales.nhs.uk

Appendix two – summary of the reporting and meeting requirements

What is the requirement	Responsibility	Activity
Financial reporting of VPAG spend	Named lead(s) with support and oversight through local organisation governance structure	• Submit monthly up-to-date financial report to the national research funding team and respond to any queries • Attend monthly finance meetings with the national research funding team
Financial reporting of commercial income	Named lead(s) with support and oversight through local organisation governance structure	• Submit quarterly reports of commercial income and expenditure to the national research funding team • Attend quarterly performance meetings with the national research delivery team
Report progress against the SMART and UK VPAG/CRDC metrics	Named lead(s) with support and oversight through local organisation governance structure	• Submit quarterly performance progress report against the SMART objectives and UK/CRDC metrics • Attend quarterly performance meetings with the national research delivery team
Upload required data to the Local Portfolio Management System (LPMS) for all commercial studies	Named lead(s) with support and oversight through local organisation governance structure	• Upload minimal data set data onto LPMS for commercial studies at least monthly