CASE/0646/06/25

VOLUNTARY ADMISSION BY MODERNA

Approval of payments

CASE SUMMARY

This case was in relation to a voluntary admission by Moderna in relation to the approval, oversight and failure to certify eight payments. Moderna submitted the payments were grants and were aligned to its commitment to support UK government-led research and innovation including the Vaccine Innovation Fund, UK grants for UK universities and research programmes.

Moderna admitted breaches of Clauses 8.3 (Certification of Donations, Grants and Benefits in Kind), 23.2 (Requirements for Grants), and 5.1 (Maintaining High Standards) of the 2024 Code.

The outcome under the 2024 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 8.3(x5) and 23.2 (x5)	**Failing to certify the written agreement for donations and grants**

No Breach of Clause 8.3(x3) and 23.2 (x3)	**Requirement to certify the written agreement for donations and grants**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A voluntary admission was received from Moderna Biotech UK Ltd.

VOLUNTARY ADMISSION

The voluntary admission wording is reproduced below with some typographical errors corrected:

> "Moderna takes its responsibility for compliance with all applicable laws and regulations including the ABPI Code of Practice ('Code') very seriously. We continuously endeavour to maintain high standards in all our activities.
>
> During our preparations for an internal audit this week, it has come to light that certain grants issued by Moderna UK do not fully meet the procedural and administrative requirements of the Code. It is important to clarify that the grants themselves are aligned

with our commitment to support UK Government-led research and innovation; the issues identified relate to the *process* of their approval and oversight, rather than their fundamental nature or purpose. Therefore, as set out in paragraph 5.14 of the PMCPA Constitution and Procedure, Moderna is formally submitting a Voluntary Admission for the Authority's consideration under the complaints procedure.

The grants in question have been provided by Moderna in accordance with its commitment to the UK Government to invest substantial funding in UK-based research and development (R&D) activities over a 10-year period [link to government website]. This commitment includes a pledge to fund grants for the Vaccine Innovation Fund, UK universities, including PhD places and research programmes. Discussions regarding these grants commenced prior to the Moderna UK affiliate becoming a member of the ABPI, initiated by Moderna's global headquarters based in the U.S. Due to the initial structure of this program, particularly where oversight and grant allocation decisions are administered by independent panels or third-party bodies, certain grants were not fully integrated into UK processes for approval and oversight, including certification by a UK final signatory. The grants at issue were signed in late 2024 and early 2025 (with payments made in 2025).

Moderna believes it has breached the requirements of Clauses 8.3 (Donations, Grants and Benefits in Kind), 23.2 (Requirements for Grants to Institutions, Organizations, or Associations), and 5.1 (Maintaining High Standards) of the 2024 Code. We confirm that Moderna has declared all grants as required under Clauses 23.2, 28.1, and 28.2 of the 2024 Code.

Moderna UK remains steadfastly committed to the highest standards of compliance and transparency and awaits your response and advice on the appropriate next steps."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 23.2, 8.3 and 5.1 of the 2024 Code.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

"We acknowledge receipt of your letter dated 8 July 2025 with the accompanying request for further information in respect of our voluntary admission concerning grant-related governance. Please find below our response addressing the queries raised in your letter and providing further information. [Moderna highlighted certain parts of its response that it considered to be commercially sensitive]

1. Summary

In December 2022, Moderna committed to the UK Government [link to government website] to invest substantial funding in UK-based research and development (R&D) activities. This includes running a significant number of clinical trials in the UK and a pledge to fund grants for UK universities, including PhD places and research programmes.

Whilst carrying out an internal review of such grant-related activities, it has been identified that certain grants committed to since April 2024 and paid for (or pending payment) in

2025 (including awards under the Vaccine Innovation Fund and other Moderna-funded academic programmes [sensitive details]) were not certified by a UK Final Medical Signatory

We therefore consider that Clauses 8.3 and 5.1 to have been breached.

2. Copies of the grants in question
[Confidential copies were provided]

3. Details of each grant request, review and approval

	Recipient	Location	Date of Payment (dd/mm/yyyy)	Contract ID	Total Contracted Amount
1	**Named teaching hospitals NHS Trust**	[Provided]	19/3/2025	[Provided]	[Provided]
2	**Named NHS Foundation Trust**	[Provided]	24/1/2025	[Provided]	[Provided]
3	**Named University Hospitals NHS Foundation Trust**	[Provided]	26/2/2025	[Provided]	[Provided]
4	**Named University Hospitals NHS Trust**	[Provided]	9/4/2025	[Provided]	[Provided]
6	**Named regional Health Board**	[Provided]	11/3/2025	[Provided]	[Provided]
7	**University PhD**	[Provided]	10/01/2025	[Provided]	[Provided]
8	**University Fellowship**	[Provided]	Not yet paid	[Provided]	[Provided]
9	**Mobile research vehicle grant submission - medical centre and hospital**	[Provided]	Not yet paid	[Provided]	[Provided]

4. A copy of the relevant grant SOP/policy at the time the Grant contracts in question were signed

[Provided]

5. Details of any relevant company or third-party instructions related to the grants in question

[Moderna referred to the grants and its relationship with the UK government]. Moderna has agreed to invest into the Vaccine Innovation Fund (VIF) to support the

strengthening of the UK's vaccine research network and immunotyping capabilities. Funding has been provided directly from Moderna to the recipients following a detailed selection criteria through the relevant committees. (Please note that PhD and Fellowship funding follows a separate governance process)

The following committees were created to determine the allocation of VIF funds and subsequently provide oversight of the use of the same.

The applications, for grants 1-6 (table above), were submitted via the vaccine innovation fund website (see attached screenshots). This website was created and supported by the NIHR to provide information for all VIF applications. Instructions were provided on the application process, project scope and eligibility criteria (see attached PDF). Applications were submitted directly to the NIHR via the VIF Research Management System (RMS). After discussions with NIHR, it was decided that Moderna would contract directly with VIF awardees selected by NIHR's review panel (process outlined below), with a key consideration being the enhanced payment and delivery flexibility this model allows (see attached PDF).

VIF grant selection and governance process:

R&D steering group

[Moderna provided details of the governance group which consisted of members of Moderna R&D (in a non-voting capacity) and representatives from government departments and agencies as well as other relevant research and clinical institutions].

Vaccine Innovation Pathway and Fund Coordination Group (VIPFCG)

- [Moderna provided details of group members].
- Role: Review and approve external applications for funding from the Clinical Trials VIF budget. For those Grants included in the scope of this voluntary admission, Moderna representatives have attended only in a non-voting capacity with respect to determining whether an application was successful or not.

Individual Contract approval and execution

- Moderna's relevant internal functional groups (e.g. R&D, Medical, Legal and Finance).
- It was determined that once the R&D Steering Committee had considered the applications for funding and determined who was to be awarded such funding, Moderna would contract directly with the recipient by way of a Grant Agreement.

	Recipient	Application process	Governance Process
1	**Named teaching hospitals NHS Trust**	Via VIF website [link provided]	R&D Steering Group in the form set out above. See attached.
2	**Named NHS Foundation Trust**	Via VIF website	R&D Steering Group in the form set out above. See attached.

3	**Named University Hospitals NHS Foundation Trust**	Via VIF website	R&D Steering Group in the form set out above. See attached.
4	**Named University Hospitals NHS Trust**	Via VIF website	R&D Steering Group in the form set out above. See attached.
6	**Named regional Health Board**	Via VIF website	R&D Steering Group in the form set out above. See attached.
7	**University PhD**	Request received directly	A Grant Request Letter for funding was submitted to Moderna by the University and on official letterhead [Moderna referred to relevant correspondence]. This letter was forwarded to Moderna's Grant Review Committee on 17 January 2024 by an employee in the R&D strategy group. In the absence of a response from the GRC mailbox, it was instead reviewed by the R&D group with medical in copy and receiving executive level sign off but without ABPI Signatory certification.
8	**University Fellowship**	Request received directly	Moderna's Global Fellowship Scheme - see attached and CAPA.
9	**Mobile research vehicle grant submission - medical centre and hospital**	See below	R&D Steering Group in the form set out above. See attached.

Grant submission for Mobile Research Vehicles: [medical centre and hospital] (grant 9)

[Moderna provided details of a funding request for mobile research vehicles from the NIHR for two sites].

6. A copy of your internal investigation into the matter, including root cause analysis, steps taken to ensure all gaps have been identified, and details of the corrective and preventative actions (CAPA) (please include a clear timeline of events).

- **January 2023**: Moderna UK became a member of the ABPI and subject to full compliance with the ABPI Code of Practice.

- **2023–2025**: Moderna UK supported grant-based activities through:

- The Vaccine Innovation Fund (VIF), [Moderna explained how the VIF worked] and

- Separate internally governed grant programmes [sensitive details] such as through funding fellowships and PhDs, which were approved through cross-functional internal processes, but without Medical signatory certification.

June 2025

- **13 June:** When compiling a spend activities log from 1 January 2025 for the purposes of submission to auditors, a potential gap was identified and raised with ABPI signatory. Initial internal discussion continued and actions commenced to identify potential gaps in UK signatory oversight for certain R&D grants linked to the Resilience R&D programme.

- **18 June:** Confirmation that certain UK-based grants had not been certified by a UK medical signatory as required under Clause 8 of the Code.

- **21 June:** Internal alignment and review with relevant functions involved to submit a Voluntary Admission to the PMCPA ahead of the scheduled audit.

- **24–26 June:** Drafting and review of initial Voluntary Admission notification letter; simultaneous identification and analysis of gaps in the Grant review further PMCPA response.

- **26 June:** Updated UK-specific Grants SOP (draft v2.0) submitted for urgent revision and approval to include UK specific requirements, namely medical signatory approval.

- **27 June:** Voluntary Admission submitted to the PMCPA, signed by the UK General Manager.

July 2025

- **1 July:** Updated Grants SOP (v2.0) issued, including a UK certification requirement aligned with Clause 23.2.

- **2 July:** PMCPA audit in London, followed by a subsequent material request.

- **8 July:** PMCPA responded to the Voluntary Admission, requesting further investigation details, supporting documentation, and a response by 30 July 2025 (later extended to 19 August 2025).

- **10–15 July:** Task assignments and SharePoint workspace created to support drafting of the formal response and coordination of supporting materials (SOPs, grant documents, timelines, CAPAs).

- **16 July:** All relevant documents (VA letter, PMCPA response, SOP v2.0) centralized in the SharePoint folder for structured collaboration.

- **21 July:** Root cause and CAPA measures formally reviewed and logged during the UK Compliance Committee session. Actions outlined for further enhancement to governance processes and captured in Gap Analysis.

- **23 July:** Continued review and implementation of corrective actions, including ensuring the VA and subsequent actions are being captured centrally. Co-ordinating with global compliance and medical functions to implement appropriate corrective actions cross-functionally and on a global basis, including ensuring routing is consistent for relevant activities through ABPI signatories. Some impact to progress due to a significant number of individuals concerned on leave, including UK Medical Director.

August 2025

- **1 August:** Discussion and agreement between Compliance and Medical functions to establish an interim UK-specific process for review, using SharePoint tracking and mandatory UK signatory review.

- **4 August:** Finalisation of two new compliance training modules for all UK staff:

    - "Responsible Social Media Use in Accordance with the ABPI Code"

    - "Introduction to the ABPI Code of Practice for Moderna UK"

- **15 August:** Communication sent from GM to all UK Staff to update on Audit and to set out importance of Medical Signatory review and approval.

- **Certification Pathway**: Further to our review of the prior grant agreements made since January 2023, we confirm that the only material non-compliance identified is the absence of prior certification by a UK final signatory at the point of execution. In all other respects, the agreements as signed already contained the substantive safeguards expected under the Code - explicit non-promotion/no-inducement wording, clear recipient independence over content and delivery, and acknowledgement of support - albeit certain transparency elements (Disclosure UK) were not expressly set out in the body text. As corrective action, we have executed (or are executing) a short ABPI Code Compliance Statement – Grant Agreement Addendum for each agreement to regularise certification, incorporate an explicit Disclosure UK undertaking for HCOs, formalise public-facing non-promotion, and correct minor drafting inconsistencies; retrospective certification has been completed by a nominated UK final signatory. No patient or public risk has been identified and we have found no evidence of inducement or promotional influence; accordingly, we consider this a procedural lapse confined to certification that is now rectified

- **Platform Controls**: A centralised repository is being created and implemented to ensure Medical signatory certification in alignment with ABPI Clause 8 for all UK grants.

- **Process and Training Updates**: Governance documents and training materials are being revised to clarify certification and disclosure responsibilities for grant activities.

To confirm, Moderna believes it has breached the requirements of Clauses 8.3 (through a lack of certification in advance), and 5.1 (Maintaining High Standards) of the 2024 Code. We no longer believe 23.2 has been breached. Moderna UK is fully committed to maintaining the highest standards of integrity and transparency under the ABPI Code of Practice. We acknowledge the importance of clear process adherence and have taken action to ensure appropriate certification and disclosure controls are implemented moving forward."

PANEL RULING

This case concerned a voluntary admission by Moderna in relation to the approval and oversight and therefore failure to certify certain grants it had issued which were aligned to its commitment to support UK government-led research and innovation including the Vaccine Innovation Fund, UK grants for UK universities and research programmes.

The Panel considered that the voluntary admission was limited to Moderna's failure to certify certain grants rather than broader compliance considerations. Moderna admitted breaches of Clauses 8.3 (Certification of Donations, Grants and Benefits in Kind), 23.2 (Requirements for Grants), and 5.1 (Maintaining High Standards) of the 2024 Code.

Moderna identified eight grants at issue; five to hospitals and a health board, two for a university PhD and fellowship respectively, and one to a medical centre, which ranged in value from approximately £39,000 to £424,000.

The Panel therefore had to decide whether each of the payments met the definition of donations and grants as set out at Clause 23.1 of the Code, namely they were funds, benefits in kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return. Clause 8.3 and Clause 23.2 required that the written agreement for donations and grants be certified. The Panel bore in mind that there were additional requirements for those payments that satisfied the definition in Clause 23.1, namely they had to satisfy Clause 23.2 including the stipulation that donations and grants should not be an inducement to prescribe, should be prospective in nature, and should not bear the name of any medicine

Moderna had agreed to invest into the Vaccine Innovation Fund (VIF), to support the strengthening of the UK's vaccine research network and immunotyping capabilities. As agreed with the National Institute for Health and Care Research (NIHR) funding was provided directly from Moderna to the recipients following a detailed selection criteria through relevant committees. The PhD and Fellowship funding followed a separate governance process. The Panel bore in mind that such funding was a legitimate activity, but companies had to ensure that relevant payments that fell within the scope of the Code complied with it.

The Panel considered that it was important for companies to decide at the outset how the funding and arrangements ought to be classified under the Code. Moderna had not argued that the funding was anything other than a grant payment. It was unclear to the Panel whether other classifications such as sponsorships or collaborative working had been considered.

Vaccine Innovation Fund website applications

Five of the grant applications at issue were made through the VIF website which was created and supported by the NIHR to provide information for all VIF applications including a 2024 competition. The website guidance explained that applications were submitted directly to NIHR for it to consider under its governance and selection process. A Steering Group agreed priorities for Moderna's investment before referring to a Coordination Group for review and approval of external applications for funding from the clinical trials VIF budget. The Panel bore in mind the membership of each committee as outlined in Moderna's response, noting that in relation to each and their consideration of the grants in question, Moderna representatives attended in a non-voting capacity.

The Panel noted that the preamble to the grant agreements in question stated that the relevant applications were approved by the NIHR Review Panel and ratified by a sub-group which Moderna co-chairs. Moderna explained that the Steering Committee would consider the applications for funding and determined who was to be awarded such funding. The Panel also noted the minutes dated 27 June of the Coordination group which made it clear that the ultimate decision on how to invest the fund resided with Moderna and the ultimate purpose of that group was to make recommendations.

The Panel noted that the selection criteria according to the VIF application guidance included: the quality and breadth of the proposed innovation project including impact measures and the potential for the project to be sustained and scaled up across the UK; the strength of the plan for the proposed innovation project including leadership and governance arrangements and plans to support skills and workforce development for clinical trials of vaccines and cancer therapeutics; and the strength of partnerships and collaborations including NIHR funded research infrastructure. The 2024 VIF competition funding call had two challenges:

1. To develop capacity and capability in clinical trials pharmacy with a focus on developing and testing novel models for delivering clinical trials of advanced therapy medicinal products (ATMPs). The challenge referred to mRNA technology, which had been classed by the regulators as an ATMP.
2. To widen patient participation in clinical trials of vaccines for infectious diseases. The development of innovative partnerships with non-hospital settings such as GP practices and care homes was encouraged to accelerate the set-up and delivery of clinical trials of vaccines for infectious disease.

The application guidance stated that after the independent selection panel had reviewed and made recommendations on the allocation of funding the UK Vaccine Innovation Pathway (VIP), the Programme Management Office (PMO) confirmed successful projects. It further stated that after discussions with NIHR, it was decided that Moderna, as the source funder, would contract directly with VIF awardees selected by NIHR's review panel with a key consideration being the enhanced payment and delivery flexibility.

The Panel had to decide whether each of the five VIF grants satisfied the definition of donations and grants as set out in Clause 23.1 of the Code such that they required certification under Clauses 23.2 and 8.3.

VIF grants

The five grant recipients and the purpose of the grant, as reflected in their respective agreements, is set out below.

- Named teaching hospitals NHS Trust - to create a seamless research infrastructure for vaccine trials across tertiary, secondary, community and primary care.
- Named NHS Foundation Trust - to establish a dedicated pharmacy rapid vaccine taskforce to work in new ways to prepare and deliver cancer vaccines at patients' bedsides.
- Named University Hospitals NHS Foundation Trust- to develop and innovative an agile model of regional integrated working to accelerate and increase the capacity and reach of vaccine research.
- Named University Hospitals NHS Trust - to develop an agile technical officer team, with vaccinator capability, that will increase regional capacity moving staff to where the work is, with the intent to widen and increase trial participation.
- Named regional Health Board - to develop and test best practice guidance for the design and conduct of vaccine trials recruiting care home residents.

The Panel observed the project application form appended to the agreements stated:

> "For ABPI compliance, exhibit A must include the following if not already covered within the application form:
>
> - description and objective of the project, including how it will support healthcare, scientific research or education
> - The extent to which this grant extends beyond the grant recipient: the names of the organizations/parties involved and their respective roles
> - The time frame for spending of funds
>
> The amount of funding and, where possible, a full breakdown of cost."

The Panel bore in mind that Moderna had submitted that each project was funded by way of a grant and had not formally classified any of the projects as research or provided a copy of a research protocol. The Panel had very limited information about the projects but queried whether the details of the projects as set out in the appendix to each agreement might be service evaluation, improvement and development rather than formal research. The Panel did not seek to classify the activities under the Code, other than deciding whether they satisfied the definition of a grant in Clause 23.1 and thus required certification as a donation and grant.

Common contractual terms

The Panel noted that each of the five grants had similar contractual terms and reviewed the common terms in relation to Clause 23 and the requirements for donations and grants.

The Panel bore in mind Moderna's submission that other than certification, in all other respects, the agreements as signed already contained the substantive safeguards expected under the Code - explicit non-promotion/no-inducement wording, clear recipient independence over content and delivery, and acknowledgement of support.

Section 4 of each agreement, Project Content, provided that the purpose of the Project was to test a service improvement idea that, if successful, would be able to be scaled up to benefit the UK Vaccine Innovation Pathway. It further provided that these ideas were not specific to the products or candidates of any specific Sponsor and that the grant recipient was responsible for exercising full control over the content of the Project, its planning and execution. The grant recipient would ensure that the Project was free of commercial bias for or against any product. The Project would not discuss or promote Moderna's products or product candidates, directly or indirectly. Moderna has not and would not direct or influence the content of the Project (including any materials). Section 4 further stated that within ninety (90) days of completion of the Project, the final grant recipient shall provide a copy of the final Project materials to Moderna.

The Panel considered that the arrangements as set out in the five agreements were not an inducement to recommend or prescribe, purchase, supply, sell, or administer specific medicines as prohibited by Clause 23.2 and were prospective in nature.

Certification

The Panel noted that the projects were all in the context of clinical trial vaccine initiatives, with goals such as service enhancements to support the delivery of vaccines, infrastructure development, taskforce development, regional integrated working, and development of best practice guidance for care home residents.

The Panel considered on the information before it that each of the five payments was given for the purpose of supporting healthcare, scientific research or education as required by Clause 23.1. They did not appear to be for any Moderna specific clinical trials or research but rather to develop or test potential improvements for vaccine delivery and frameworks for the conduct of clinical trials which if scalable could potentially support UK vaccine infrastructure.

Considering the overall arrangements as described above, the Panel considered that each grant broadly appeared to meet the requirements in Clause 23.1. The Panel acknowledged that each agreement was based on a standard grant template that contained a mandatory requirement to provide a final copy of the project materials to Moderna within 90 days of completion. Given the definition of a donation or grant as set out in Clause 23.1, the Panel queried whether this meant there may have been a consequent obligation on the recipient to provide a good or service to the benefit of Moderna, undermining the classification of it as a grant. The Panel, however, considered the term "project materials" to be ambiguous. No evidence had been provided as to what such materials constituted, the intent for their use or whether they conferred any benefit to Moderna; it was not sufficiently clear whether the final project materials would be such that Moderna was receiving a good or service to its benefit in return. It was possible that the final project materials were for Moderna to undertake due diligence such as to demonstrate that the funds had been used for the intended purpose as set out in Appendix A to the agreements.

Given the position was unclear, the Panel decided, on balance, that there was insufficient information to demonstrate these arrangements were not grants. The Panel noted the unusual circumstances whereby the grants formed part of broader commitments made as part of Moderna's partnership with the UK government and considered that Moderna should ensure that all arrangements comply with the Code. The Panel accepted Moderna's submission that the arrangements constituted grants and therefore required certification. In relation to the scope of the voluntary admission by Moderna, the Panel ruled **a breach of Clauses 23.2 and 8.3** for each grant as submitted by Moderna.

Mobile research vehicle grant submission - medical centre and hospital

The Panel noted Moderna's submission that the funding request for mobile research vehicles from the VIF did not originate from the 2024 VIF competition but from an associated national research body. The grant agreement was with a clinical research company based at a named medical centre. A further related agreement with a hospital was expected to be signed later in 2025. Both sites directly contracted with the mobile research vehicle provider and Moderna then contracted with the sites to fund the hire cost.

Moderna referred to the minutes of the Steering Group in relation to the approval of the grant although a copy was not before the Panel, the minutes of another committee did refer to the medical centre but in relation to what appeared to be a different funding arrangement. In the absence of any evidence to the contrary the Panel based its ruling on the funding arrangements described in the agreement.

According to the grant agreement, the goal was for the lease of a mobile research unit to support follow-up visits for the Moderna Nova 301 vaccine study. The project description in the appendix of the agreement described the Nova 301 study as a cutting-edge commercial research study that aimed to make clinical research more inclusive by expanding recruitment beyond hospital settings. As the first commercial vaccine study to pilot mobile research units, it was described as setting a precedent for the future of UK clinical research by addressing recruitment challenges and diversity gaps. A supporting email, dated 14 February 2025, described the financial support as innovation for the trial in its post recruitment phase.

The Panel noted that the grant agreement was based on a standard template and closely similar to those for the five grants outlined above, with the requirement to provide final project materials within 90 days of completion. While the Panel queried whether this was a consequent obligation on the recipient, it nonetheless considered the clause to be of limited practical relevance in this context given the funding related directly and solely to the cost of leasing of vehicles for a Moderna trial.

The Panel considered that the arrangements differed from the other VIF applications considered above. In this case, the funding for mobile research vehicles was clearly linked to a specific Moderna vaccine trial. The Panel considered that the acceptability of expenditure integral to a company sponsored trial would not normally be considered wholly independently from that trial. It was unclear on the limited information before the Panel whether this project was of broader benefit beyond the clinical trial expenditure. Further, reimbursement of a clinical trial expense for a company sponsored trial would not, in the Panel's view, satisfy the definition of a grant at Clause 23.1. It was wholly unclear why Moderna had classified the arrangements as a grant. Clause 24, Contracted Services, included research and development work, including clinical trials and associated expenses.

Based on the information before it, the Panel considered the funding for mobile research vehicles for Moderna's Nova 301 study was not a grant as set out in Clause 23.1 of the Code and therefore did not need to be certified. **No breach of Clauses 23.2 and 8.3** was ruled in relation to the failure to certify the grant agreement.

Whilst the voluntary admission on this point also referred to a hospital, the Panel considered the contract had not been executed at the time of the voluntary admission and thus made no ruling in relation to that agreement.

The Panel acknowledged that it was important that arrangements were correctly classified under the Code at the outset and the appropriate approval mechanism identified. The Panel

also accepted that a company might decide to certify materials/arrangements even if certification was not required under the Code.

University PhD

The Panel noted that the funding request was received directly in the form of a grant request letter submitted to Moderna by a named university at the request of a national health organisation to whom commitments had been made to invest funds into the VIF. Moderna submitted it was reviewed by the R&D group with medical in copy, receiving executive level sign off, but not certification.

According to the university letter of understanding, the Moderna-funded PhD concerned the "Development of Agent-based Modelling for Prospective and Retrospective Assessment of Pandemic Interventions" which aimed to further develop an individual-level model, originally developed during the pandemic at a different university, which modelled the entire population. The letter included the understanding that selection of the content, appropriate collaborators and logistical elements for the proposed work and educational program would be independent of any Moderna influence. Further the research was intended to lead to publication.

The Panel bore in mind that the studentship agreement was between the university and Moderna, the university paid a student stipend out of the funds which also covered matters such as staff time and university fees. Exhibit A to the agreement described the project as a collaboration between the named university and a national health body including collaborators from three other named universities.

The studentship agreement provided that the Program will not promote Moderna's products or product candidates, directly or indirectly. Moderna has not and will not direct or influence the content of the Program (including any Materials). Grant Recipient agrees that when a Moderna product candidate or product is to be the subject of discussion in the Program (other than in an incidental discussion), Grant Recipient will ensure that any related data is objectively selected and presented, including but not limited to the fair representation and presentation of both favourable and unfavourable information about the product candidates or products, as well as a balanced discussion of the prevailing body of scientific information with respect to such product candidates or products and alternative treatment options.

The Panel noted that the agreement was titled as a studentship agreement rather than a grant agreement and included provisions that the university retained ownership of any arising intellectual property (IP). Moderna was granted a non-exclusive, royalty-free license to use such IP, including sub-licensing rights to affiliates. The agreement also included mutual rights for both parties to review proposed publications and, where appropriate, request reasonable delays to protect confidential information or arising intellectual property.

While the Panel questioned whether such arrangements might constitute a sponsorship, it was not possible to determine the classification in the absence of sufficient information. The sole matter for the Panel to consider was whether the arrangements met the definition of a grant under Clause 23.1 and thus required certification.

The Panel noted that the agreement, similarly to those outlined above, included a mandatory requirement to provide a copy of the final program materials within 90 days of completion of the program in Section 5, Program Content. The Panel queried whether this requirement, in combination with the intellectual property rights granted to Moderna, amounted to a consequent

obligation on the recipient to provide a benefit in return for funding, which went beyond due diligence. The Panel considered that this agreement was different to those for the VIF grants described above on this point as there was an additional clear consequent obligation on the recipient university. Based on the evidence before it, the Panel concluded that the arrangement did not satisfy the definition of a grant under Clause 23.1 and therefore did not require certification as a grant. **No breach of Clauses 23.2 or 8.3 was ruled** in relation to the failure to certify the studentship agreement.

The Panel acknowledged the narrow nature of its ruling above. It did not seek to classify the arrangements based on the nature of the admission and the limited information before it. In the Panel's view, its ruling did not mean that the PhD did not need to be approved under the Code, rather that the arrangements needed to be correctly classified and approved accordingly.

University Fellowship

At the date of the voluntary admission, whilst the research fellowship agreement 'Towards human cell and tissue targeted mRNA vaccine delivery' had been signed, the funding had not been provided. The fellowship application provided that a primary aim of the fellowship was to conduct high-quality and publishable research relating to mRNA vaccines and the fellowship agreement provided that Moderna would provide the grant to the Institution for the conduct of the research. Section 4 of the fellowship agreement, Reports and Audits: Use of Research Data, stated that Moderna would be provided with a final research report and an irrevocable, royalty-free, worldwide licence to use the research data for its internal research and development purposes. Any changes to the research plan required Moderna's written approval, as stated in Section 5.

The Panel noted that Moderna had not submitted that this was clinical research which would trigger certain additional governance requirements and it had provided limited information about the arrangements. In the Panel's view, it was important that arrangements be reviewed and classified correctly at the outset so that the appropriate governance framework was implemented.

The Panel accepted that certain aspects of research and development fell outside the scope of the Code and further bore in mind that Clause 24, Contracted Services, applied to contracted services between pharmaceutical companies and healthcare organisations including for involvement in medical/scientific studies and clinical trials. Moderna had submitted that each project was funded by way of a grant. In the Panel's view, bearing in mind the nature of the fellowship, it appeared that the mandatory requirements for the research fellow/university to provide the final research report, combined with an irrevocable licence to use the report to Moderna, was a benefit that went beyond due diligence to ensure that the fellowship fund was used for the intended purpose. The Panel considered that this agreement was different to those for the VIF grants described above on this point as there was an additional clear consequent obligation on the recipient university. The Panel also noted that unlike the agreement for the PhD, the individual who would benefit from the fellowship had signed the Fellowship agreement alongside the university and Moderna.

The Panel therefore considered that the fellowship fund was not a donation and grant as defined in Clause 23.1 of the Code and therefore did not need to be certified as set out in Clauses 8.3 and 23.2. **No breach of Clauses 23.2 and 8.3** was ruled in relation to the failure to certify the fellowship as a grant.

The Panel acknowledged the narrow nature of its ruling above. It did not seek to classify the arrangements given the nature of the admission and the limited information before it. The Panel's ruling simply determined that the funding did not need to be certified as a grant under the Code.

Clause 5.1

The Panel noted Moderna's submission that due to the initial structure of this programme, particularly where oversight and grant allocation decisions are administered by independent panels or third-party bodies, certain grants were not fully integrated into UK processes for approval and oversight, including certification by a UK final signatory.

The Panel was reassured that once Moderna became aware of this matter it had taken steps to improve compliance. Nonetheless, the Panel had to consider whether high standards had been maintained at the time the agreements were executed. The Panel observed that according to the VIF website as part of a wide strategic partnership with the UK government 'Moderna had established the VIF, a multimillion-pound fund' to invest in sustaining and enhancing the UK capabilities in vaccine research beyond the immediate crisis of the pandemic. Bearing in mind the significant sums involved, the high-profile nature of the VIF fund, and that the activities that would involve interactions with healthcare organisations, it was very difficult to understand why approval under the Code had not been considered. In the Panel's view, high standards had not been maintained and **a breach of Clause 5.1 was ruled**.

Complaint received **27 June 2025**

Case completed **7 October 2025**