Advanced Therapy Investigational Medicinal Product Protocol Guidance Document

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Advanced Therapy Treatment Centres

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Table of Contents

Introduction

Scope

This is a protocol guidance document that can be used to inform the writing and development of Advanced Therapy Investigational Medicinal Product (ATIMP) specific protocols targeted for trial delivery in the United Kingdom (UK).

It is intended that this guide be used in conjunction with a protocol template such as the Health Research Authority (HRA) protocol template, TransCelerate protocol template or the contents of a protocol as specified within Appendix B of the current ICH E6(R3) Guidelines.

This protocol guidance document aligns with relevant regulatory guidelines and considers various ATIMP products. A range of stakeholders will find this guidance document useful, but small sized or ATIMP naive sponsor companies, Clinical Research Organizations (CROs) and investigator-initiated Studies (run by Clinicians and Academics) will find this document of most value.

This protocol guidance document is composed of guidelines and recommended reading specific to key protocol sections that are nuanced for ATIMP trials.

Rationale

The Advanced Therapy Treatment Centre (ATTC) network has determined there is an abundance of CTIMP (Clinical Trial of an Investigational Medicinal Product) protocol templates and guidance documents, but a lack of guidance documents tailored to ATIMPs. The creation of an ATIMP specific protocol guidance document will drive standardisation within the UK and help accelerate trial start up times.

Authorship

This guide has been developed by the ATTC network, with contributions from leading National Health Service (NHS) organisations. The network is funded by the National Institute for Health and Care Research (NIHR), is coordinated by the Cell and Gene Therapy Catapult (CGTC) and operates under the oversight of Innovate UK (IUK).

Acknowledgements

This guidance document was developed in consultation with key bodies within the ATMP UK landscape including the NIHR, NHS Research Scotland (NRS), Health and Care Research Wales, Specialist Pharmacy Service Pan-UK Pharmacy Working Group for ATMPs, an Industry Advisory Group overseen by Cell and Gene Therapy Catapult, Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA).

Disclaimer

This document is designed to be used as a guide by ATMP developers. The authoring groups will aim to ensure that the information contained within this document is regularly reviewed. Users are responsible for verifying the content contained within this document is correct and applicable according to the Advanced Therapy Medicinal Product (ATMP) UK landscape.

Document History

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V1.0	09Jan2026	First Version

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1. Protocol Synopsis

The protocol synopsis (sometimes referred to as the trial summary) provides a concise overview of the full clinical protocol. Early inclusion of ATIMP-specific information in this section is essential, as ATIMP protocols are subject to unique regulations, specialised logistics and infrastructure requirements. This enables timely engagement and consultation with hospital staff and governance/regulatory authorities. Additionally, it is recommended to include trial locations and third-party organisations involved in the trial, since the synopsis is often used in the initial stages of a trial to assess costings for the sponsor and evaluate feasibility with participating sites.

The ATIMP product classification should also be specified within the document. Other details such as product type, manufacturer, handling, administration and disposal, Genetically Modified Organism (GMO) risk categorisation, trial design, comparator drug (if applicable), cohorts, safety review, data review, schedule of assessments, reference to trial timelines, need for Long Term Follow Up (LTFU), efficacy endpoints and number of participating centres/participants should also be included.

2. Protocol Introduction

a. Background

This section should provide a concise overview of the ATIMP technology, including GMO risk categorisation, mechanism of action and relevant research findings from prior clinical, pre-clinical and non-clinical studies. It should be as succinct as possible (limited to no more than two pages) and should avoid duplicating content already presented in the Investigator Brochure (IB). Where appropriate, cross-referencing the IB is recommended. Appropriate references to published literature on the disease or condition, its current treatment and the use of the Investigational Product (IP) should be included.

b. Rationale

This portion of the protocol should include a clear justification for the chosen trial design, particularly where limitations in recruitment size or participant selection exist (e.g. small populations in rare disease indications). Adequate description of the rationale for the trial design will address potential challenges between the proposed trial design and other probable trial designs.

Developers should explain why the ATIMP may offer advantages over the current standard of care, for example improved target specificity and reduced adverse events compared to conventional treatment. Additionally, rationale for the selected route of administration, planned dose, treatment duration and choice of controls (if applicable) should be included.

c. Risk-Benefit Assessment for Trial Participants

A clear and comprehensive overview of the expected benefits and potential risks associated with the specific ATIMP should be included in the protocol. This information must guide the development of appropriate safety measures and risk mitigation strategies. In addition, the protocol should include a risk–benefit statement regarding site selection, as not all hospitals or pharmacies have the necessary infrastructure for GMO management, apheresis or other specialised requirements.

The protocol should explain how participants will be made aware if the ATIMP treatment is irreversible or may result in permanent changes to their body, such as genetic modification or long-term cellular effects. The protocol should also provide specific guidance on contraception, potential exposure to vulnerable individuals or those requiring special consideration (including children, pregnant women and vulnerable adults) and address considerations related to egg harvesting, sperm donation and any associated risks to future unborn children.

For gene therapies using viral vectors, protocols must assess risks such as genome integration, viral shedding, systemic distribution and long-term persistence of the product. Similarly, any treatment specific risks should be detailed (e.g. Cytokine Release Syndrome (CRS) and Immune effector Cell-Associated Neurotoxicity Syndrome (ICANS) for Chimeric Antigen Receptor T-cell (CAR-T) therapies) as they require proactive monitoring and management due to their potential severity. Advice should be included on measures to be taken to treat potential treatment consequences.

3. Trial Procedures

a. Apheresis Cell Collection (where applicable)

Early engagement with the apheresis cell collection facility is advisable, particularly when apheresis cell collection is provided by a third party such as the Scottish National Blood Transfusion Service (SNBTS), Welsh Blood Service (WBS) or the National Health Service Blood and Transplant (NHSBT). This will facilitate efficient and accurate protocol design. Separate contracting between the health board or trust and the third-party service provider may also be required.

A separate document detailing the requirements for the apheresis cell collection process specific to the trial ATIMP should be developed to supplement the protocol and provide additional operational detail. This is particularly relevant given the need to ensure standardisation and consistency in cell collection procedures, critical to ensuring product quality and participant safety. To ensure high quality and full traceability of starting material, ATIMP apheresis cell collections should be controlled through a quality management system, such as evidenced by JACIE (Joint Assurance Committee of the ISCT and EMBT) certification. The

Sponsor should state in the protocol if it is a trial requirement that apheresis collection is carried out in a JACIE-certified cell collection facility.

Details should be provided regarding the regulatory requirements applicable to the apheresis cell collection facility's activities as set out in the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007, Human Tissue Act Scotland 2006 or the Human Blood (Safety and Quality) Regulations 2005 (whichever is applicable). It should be noted that the Regulation on Standards of Quality and Safety for Substances for Human Origin (SoHO) Intended for Human Application (also referred to as the SoHO Regulation) came into force in the European Union (EU) in 2024 and will take full effect from August 2027. It will apply in Northern Ireland but not (currently) Great Britain and so must also be referenced in protocols intended for use within the UK. Patient/donor safety and traceability of cells is a requirement and traceability from donor to recipient (and vice versa) must be maintained for 30 years.

References: ATTC network NHS Toolkit: Apheresis Training and Competency Manual

b. Other Tissues Collected as Starting Material (where applicable)

Starting material for ATIMP manufacture may involve tissue collection using non-apheresis methods, such as procedures in an operating theatre, outpatient clinic or whole blood sampling. These processes must be clearly defined and described within the trial protocol. An adequate level of detail must be referenced in the protocol to ensure all relevant regulatory and certification requirements are met (e.g. Human Tissue Authority (HTA) licence, with scheduled activities detailed). When cells are collected as the starting material for ATIMP manufacture, JACIE certification covers cells collected by apheresis, and from marrow, blood and tissues of interest. As such, the Sponsor should state in the protocol if it is a trial requirement that collection is carried out in a JACIE-certified facility. As with cells, tissue traceability from donor to recipient (and vice versa) must be maintained for 30 years.

c. Genetic Testing

The protocol must detail all genetic tests involved, what the information will be used for and if it holds any benefit to participants. The participants must be made aware of any genetic tests as part of the informed consent process through the Participant Information Sheet (PIS) and Informed Consent Form (ICF). 'Qualifying' consent must be given in line with Section 45 of the Human Tissue Act. The protocol should describe how genetic information will be discussed with the participant and with whom it may be shared.

For ATIMP trials, particularly those targeting rare diseases, sponsors should consider implementing separate genetic screening protocols to optimise patient identification and enrolment. Collaboration with Patient Advocacy Organisations (PAOs) is strongly encouraged to support outreach, improve trial awareness and ensure that the trial design reflects patient needs and priorities. Special considerations should be given when testing children as additional regulatory conditions may need to be met. Children are not generally tested in a clinical setting

unless they are exhibiting symptoms, so consider what action may need to be taken if the genetic test(s) required do not align with the child's symptoms.

Reference material: Research and the Human Tissue Act 2004 DNA analysis

d. Participant Withdrawal and Early Trial Termination

The stopping rules should be clearly defined in the protocol for an individual participant, trial group/cohort or for the entire trial to be paused or terminated. The stopping rules should consider Dose Limiting Toxicities (DLTs), disease progression and predefined adverse event thresholds. For example, a participant death may suspend further enrolment. Permanent trial termination may occur if adverse event reporting exceeds pre-defined frequencies or severities.

e. Long Term Follow Up

Due to the novel mechanisms of action, permanence and potential for delayed or long-term safety risks associated with ATIMPs, follow-up is needed to assess durability of therapeutic benefit, detect delayed or rare adverse effects and meet regulatory safety requirements. The sponsor should ensure inclusion of information on the requirement of any extended observation of the ATIMP effect. The design of LTFU visits (i.e. the duration, type and number of assessments) should be set up according to regulatory requirements and be informed on a case-by-case evaluation. For all ATIMP studies, particularly those involving integrating vectors, a standard follow-up period of up to 15 years is generally expected. Participants need to be aware of the commitment to LTFU during the informed consent process. Early engagement with the relevant regulatory agencies for advice and guidance on LTFU design and requirements is encouraged.

LTFU requirements in ATIMP trials can place significant burden on both sites and participants. To support retention and reduce operational strain, protocols should prioritise decentralised monitoring and remote data capture models. This enables flexible participation, improved data completeness and promotes inclusivity across geographically dispersed populations. LTFU also provides real-world evidence crucial for the refinement of treatment pathways and reimbursement decisions.

Reference material: Guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products - Scientific guideline | European Medicines Agency (EMA)

4. Trial Treatments

a. Trial Product

Clearly identifying the type of product (i.e. gene therapy, cell therapy, tissue-engineered product, genetically modified viral therapy) and its mechanism of action informs the clinical rationale, target patient population and expected outcomes of the trial. Stating the GMO classification will direct other risk assessments that may be required.

The Sponsor should outline the description of the ATIMP product, including its regulatory classification, proposed biological activity and any additional pertinent characteristics. If a fixed dose is not applicable, the anticipated dosing range should be specified. Additionally, any requirements related to the sourcing and/or preparation of donor material (if relevant) should be highlighted.

If the ATIMP includes a medical device, either as part of a combined product or as an accessory used during its administration, the protocol must outline the device's intended function, technical specifications and expected performance. Additionally, it should be indicated whether the device component adheres to applicable UK or EU medical device regulations, particularly those concerning safety and performance standards. If the device is not already a regulated device, signposting to appropriate regulations should be included.

Reference material:
https://www.hse.gov.uk/biosafety/gmo/index.htm - GMO products only
https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm - GMO products only
Advanced therapy medicinal products: regulation and licensing in UK - GOV.UK

b. Pre-Treatment

Conditioning regimens (e.g. chemotherapy and lymphodepletion) are often used to prepare the participant to receive and accept the therapy. A wash-out period may be needed to prevent drug interactions with the ATIMP and to eliminate immunosuppressive or cytotoxic drugs that could alter the product's mechanism of action.

When relevant, the sponsor should describe any preparatory interventions prior to ATIMP product administration, such as wash-out periods, conditioning regimens or pre-medications (such as anaphylaxis prophylaxis, vaccines and immunotherapy). Information on the dosing schedule should be included and details of ATIMP supply should be included in the Pharmacy Manual.

c. Dosing and Administration

The sponsor should describe the dosage, timing, duration and the planned route of administration. Information on the administration procedure for the ATIMP should be included, particularly when specific concomitant medication or surgical interventions are required. Details

should be provided regarding any required observations to be conducted both during and following administration, including whether any direct monitoring is necessary. If inpatient hospitalisation is required post-administration, the length and requirements of this should be specified within the protocol. Post-administration observations for outpatients should also be specified.

If there is a requirement for an isolation room because of viral shedding, this should be noted within the GMO risk assessment. Note that this is a required per UK and EU Genetically Modified (GM) legislation. It is recommended that a separate manual containing specific ATIMP handling, administration and disposal procedures is supplied as a supplement to the protocol. This may be within or in addition to the Pharmacy manual.

If the planned treatment cannot be administered because the participant is withdrawn from the trial (e.g. clinically unsuitable on the scheduled day, withdrawal of consent or deemed unsuitable by the Principal Investigator (PI)), the protocol must specify what will happen to the ATIMP product. The product should either be disposed of or, if appropriate consent has been obtained and documented in the ICF, used for research purposes.

In cases of apheresis, manufacturing, storage or shipping failure, which results in a non-compliance with the Investigational Medicinal Product Dossier (IMPD) or other trial-related documents, the protocol must outline the procedure for use of the IP and whether the product may be replaced. For example, in the case of manufacturing failure which results in an out-of-specification product, sponsors must assess the risk-benefit of administering the product to the waiting participant and seek approval from the relevant health authority and local regulatory agencies. The investigator must also inform the participant that the product does not meet release criteria and confirm consent before proceeding.

For cohort-based trial designs, a cohort management plan is essential to ensure equitable slot allocation, particularly when manufacturing capacity is constrained. To support safe and consistent product handling, sponsors are strongly encouraged to implement mock training sessions and “dry runs” for site staff, especially where complex IP supply chains and administration procedures are involved.

Reference Material: EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines

d. Investigational Product Management

The sponsor should provide summary data on the IP formulation, packaging, shipment, and storage requirements. Full details of the IP formulation must be included in the IMPD while drug management instructions should be specified within the pharmacy manual.
IP management requirements often change, so it is best to detail these in the pharmacy manual rather than the clinical trial protocol, which would require a formal amendment for updates. The pharmacy manual is essential for trial conduct and assessing site capability. It is recommended that the lead site pharmacy reviews the draft manual before it is finalized and distributed to sites.

The pharmacy manual should be drafted in parallel with the protocol and provided to sites with the protocol. The protocol must reference the pharmacy manual for additional details of any interactions with the local cell processing lab, storage conditions, packaging and labelling (including supply chain and shipment contents), prescription requirements, dispensing procedures and stock ordering and destruction processes. The protocol should also include guidance on the management of surplus product, specifying whether excess material may be stored for a future second dose, destroyed or used for scientific research. Any storage or secondary use of surplus product must be clearly outlined in the ICF. It is essential to detail any specialised storage conditions or facilities required, such as cryostorage, to ensure compliance and site readiness.

Reference material:
Pharmacy Manual Checklist for Clinical Trials for ATIMPs – SPS
Somatic Cell Therapy Medicinal Products – Pharmacy Institutional Readiness Guidance
In-Vivo GMO Gene Therapy Medicinal Products – Pharmacy Institutional Readiness Guidance

e. Traceability

Current regulations require that traceability records for ATIMPs be retained for 30 years following use, expiry or disposal of tissues or cells. This is significantly longer than for most medicinal products. This extended retention period should be a key consideration when drafting contracts with sites and third-party vendors. While sponsors cannot archive site files themselves, they can provide financial support and recommend secure archiving partners to ensure compliance. Many vendors typically retain records for 2–5 years, meaning sponsors must assume responsibility for long term control and storage.

Sponsors, hospitals and clinics administering ATIMPs must ensure that the product can be traced from donor or seed stock, to manufacturer and then to recipient (and vice versa). It is recommended that sponsors describe briefly in a sub-section of the protocol how compliance is demonstrated. This could be by providing participating sites and centres with documents necessary to maintain adequate traceability. This may be detailed in a separate product handling manual in respect to products that require tissue procurement or products that have personalised elements to them (e.g. ex-vivo gene therapy, tissue engineered products and cellular products).

Reference material:
The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010
Human application sector - HTA standards | Human Tissue Authority
Good Clinical Practice specific to Advanced Therapy Medicinal Products

f. Post-Treatment

Some types of ATIMPs require medications to prevent or manage emerging toxicities (e.g. IL-6 blocking antibodies such as Tocilizumab). These should be detailed within the protocol in terms of product names, treatment plans and supply arrangements.

Protocols must include clear guidance on managing potential toxicities associated with ATIMPs, such as CRS, ICANS, cytopenias, infections and secondary malignancies. The guidance may be documented within the protocol or agreed that sites may use their institutional guidelines. To inform appropriate monitoring and intervention strategies, it is essential to specify the nature and basis of these risks, whether they arise from the product class, mechanism of action, non-clinical data or previous clinical experience with similar or commercially available products.

DLTs must also be clearly defined within the protocol, along with a strategy for managing these in relation to planned dosing schedules, especially in dose-escalation studies. Effective toxicity management requires that site staff are adequately trained and that facilities are equipped to handle severe adverse events, such as access to Intensive Care Units (ICU) where necessary. The use of Data Safety Monitoring Committees (DSMC) or Safety Review Committees (SRC) is strongly recommended to oversee safety data, guide dose escalation decisions and ensure that DLTs are appropriately monitored and managed throughout the trial. Note that DSMCs and SRCs can have different remits depending on trial phase and design.

g. Concomitant and Prohibited Medications

The protocol should specify all rescue medications, challenge agents and Non-Investigational Medicinal Products (NIMP) used to assess endpoints or as background treatments, including details of product, dosage, and supply arrangements. It should also list any prohibited medications or surgical interventions including any restrictions on the use of steroids, including guidance on permitted doses.

5. Statistics & Data Handling

a. Statistics

Given the complexity and variability of ATIMPs, the statistical section should define key considerations such as when an Adverse Event (AE) becomes a Treatment Emergent AE (TEAE). The protocol must also outline strategies for handling small sample sizes, which are common due to the specificity of ATIMPs, and provide clear guidance on managing missing data or replacing participants who withdraw from the trial.

b. Pharmacovigilance

The protocol must specify processes for recording and handling doses, as dose volumes can vary significantly between participants in ATIMP trials. These variations may affect both safety and efficacy outcomes, requiring robust systems for tracking deviations and linking them to adverse event reporting. Pharmacovigilance (PV) data should integrate seamlessly with the broader data management framework to support monitoring of ATIMP specific risks such as unexpected toxicities, delayed adverse reactions and risks associated with complex manufacturing or administration steps.

6. Other Key Considerations

a. Patient and Public Involvement and Engagement

Patient and Public Involvement and Engagement (PPIE) is a crucial foundation in clinical research which ensures that patients, people with lived experience, carers and the public are actively involved in the entire research process.

When developing the research question and designing the trial, there are several key areas where patients, carers and the public can be involved which in turn may influence different sections and subsections of a protocol. These includes:

- **Trial design**
- **Development of participant materials and ongoing communications**
- **Post-Trial Access:** sponsors must consult with patients, carers and the public in determining a process for the continuation of a therapy if the intervention shows therapeutic or clinical benefit but is not yet commercially available. Access to rescue therapies must also be considered if the experimental product fails or harms. Post-trial special licences, such as managed access programs or expanded access programs, must be considered.
- **Blinding and Unblinding:** blinding and unblinding of ATIMP studies should be considered and indications for unblinding well defined due to risks associated with novel mechanisms and long-term risks of ATIMPs.
- **LTFU:** ongoing compassionate use and follow-up of patients who have been administered ATIMPs should be used to develop long term follow up trials. Sponsors are advised to follow regulatory guidelines and evaluate on a trial-specific basis when determining the length and type of a long term efficacy trial. Patients, carers and the public should also be consulted as long term monitoring for ATIMP trials is crucial in the decision making for participation, compliance and commitment to a clinical trial.
- **Genetic testing:** special attention should be given to explaining the need for genetic testing and how information gathered from these tests will be handled.
- **Manufacturing delays:** some ATIMP studies encounter manufacturing delays. This may influence the decision making process for participants. Therefore, it is recommended that patients, carers and the public are made aware of this potential during the trial design stage.
- **Equity of Access:** PPIE can provide ample considerations to promote equality, diversity and inclusion of trial participants. Considerations should be given to the schedule of assessments to minimise patient burden as much as feasibly possible.

b. Equity of Access

Promoting equity of access to ATIMP trials ensures a fair opportunity for participants to partake. The conduct of ATIMP studies typically requires specialist skills, staff training, adequate infrastructure and in-depth policies around key procedures such as apheresis, cell storage and waste management. These typically restrict the delivery of ATIMP trials to large specialist centres which may exclude participation, access or knowledge from geographic regions distant to these specialist centres. Protocol developers are recommended to:

- consider the geographical spread of sites selected to conduct a clinical trial
- consider the patient referral pathway from general practitioners, secondary care centres, local/regional multi-disciplinary meetings and local/regional recruitment platforms
- consider patient burden when devising the schedule of assessments and the requirement for in-person clinic visits
- consider providing trial participants with travel and logistical support to ensure their participation is feasible

c. Trial registries

Trial registries promote data sharing and transparency, contributing to global understanding of long-term safety and efficacy. Clinical trial registries also ensure there is LTFU of clinical trial participants should sponsors cease to operate. The protocol should state that the trial will be registered in a recognized registry as part of the UK's automatic process following Clinical Trial Application (CTA) submission. Sponsors should take care to check the accuracy of the registry record prior to publishing.

Appendices

Appendix 1: Definitions and Abbreviations

AE	Adverse Event
ATMP	Advanced Therapy Medicinal Product *Classification used to denote a medicinal product which is either a gene therapy medicinal product, a somatic cell therapy medicinal product or a tissue engineered product. Note that due to the pace of innovation in this field, this definition is likely to change.*
ATIMP	Advanced Therapy Investigational Medicinal Product *Investigational product used in clinical trials that falls under the category of advanced therapies. Unlike licensed ATMPs, ATIMPs are still under investigation and have not yet received marketing authorization.*
ATTC network	Advanced8 Therapy Treatment Centre network *UK-wide initiative aimed at accelerating the adoption of ATMPs into the NHS. It coordinates various Advanced Therapy Treatment Centres (ATTCs) across the UK, focusing on overcoming challenges in clinical trial delivery and ensuring the effective use of innovative therapies.*
CGTC	Cell and Gene Therapy Catapult
CAR-T	Chimeric Antigen Receptor T-cell
CRO	Contract Research Organisation
CRS	Cytokine Release Syndrome
CTA	Clinical Trial Application
CTIMP	Clinical Trial of an Investigational Medicinal Product
DLT	Dose Limiting Toxicity
DSMC	Data Safety Monitoring Committee
EU	European Union
GM	Genetically Modified
GMO	Genetically Modified Organism
HRA	Health Research Authority
HTA	Human Tissue Authority
IB	Investigator Brochure
ICANS	Immune effector Cell-Associated Neurotoxicity Syndrome
ICF	Informed Consent Form
ICU	Intensive Care Unit
IMPD	Investigational Medicinal Product Dossier
IP	Investigational Product
IUK	Innovate UK
JACIE	Joint Assurance Committee of the ISCT and EMBT
LTFU	Long Term Follow Up
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHSBT	National Health Service Blood and Transplant
NIHR	National Institute for Health and Care Research
NIMP	Non-Investigational Medicinal Product
NRS	NHS Research Scotland
PAO	Patient Advocacy Organisation
PPIE	Patient and Public Involvement and Engagement
PI	Principal Investigator
PIS	Participant Information Sheet
PV	Pharmacovigilance
SNBTS	Scottish National Blood Transfusion Service
SoHO	Substances of Human Origin
SRC	Safety Review Committee
TEAE	Treatment Emergent Adverse Event
UK	United Kingdom
WBS	Welsh Blood Service

Appendix 2: ICH E6(R3) Protocol Table of Contents

Below is the contents table retrieved from Appendix B. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S) of ICH E6(R3) Guidelines. The highlighted sections have been specified to indicate sections of a protocol that are highly customisable when protocol templates are being tailored specifically for ATIMPs.

B.1 General Information

B.2 Background Information

B.3 Trial Objectives and Purpose

B.4 Trial Design

B.5 Selection of Participants

B.6 Discontinuation of Trial Intervention and Participant Withdrawal from Trial

B.7 Treatment and Interventions for Participants

B.8 Assessment of Efficacy

B.9 Assessment of Safety

B.10 Statistical Considerations

B.11 Direct Access to Source Records

B.12 Quality Control and Quality Assurance

B.13 Ethics

B.14 Data Handling and Record Keeping

B.15 Financing and Insurance

B.16 Publication Policy

Appendix 3: HRA Protocol Template Table of Contents

Below is the contents table retrieved from the HRA protocol template for Clinical Trial of an Investigational Medicinal Products (CTIMPs). The highlighted sections have been specified to indicate sections of a protocol that are highly customisable when protocol templates are being tailored specifically for ATIMPs.

GENERAL INFORMATION

TITLE PAGE

RESEARCH REFERENCE NUMBERS

SIGNATURE PAGE

KEY TRIAL CONTACTS

i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS

iii. TRIAL SUMMARY

iv. FUNDING

v. ROLE OF SPONSOR AND FUNDER

vi. ROLES & RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITTEES, GROUPS AND INDIVIDUALS

vii, PROTOCOL CONTRIBUTERS

viii. KEYWORDS

ix. TRIAL FLOW CHART

SECTION

1. BACKGROUND
2. RATIONALE
3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS
4. TRIAL DESIGN
5. TRIAL SETTING
6. PARTICIPANT ELIGIBILITY CRITERIA
7. TRIAL PROCEDURES
8. TRIAL TREATMENTS
9. PHARMACOVIGILANCE
10. STATISTICS AND DATA ANALYSIS
11. DATA MANAGEMENT
12. MONITORING, AUDIT & INSPECTION
13. ETHICAL AND REGULATORY CONSIDERATIONS
14. DISSEMINATION POLICY
15. REFERENCES
16. APPENDICIES