

This Quick Guide highlights what materials should be provided by the client and what materials should be provided by the agency during the course of a Market Research (MR) project from initial contracting to project completion. Both sides of the partnership should be conscious of what's required and who should be providing what. If they have not been provided both parties should be prepared for them to be requested.

Key Principles

- Market Research must be carried out in a compliant manner
- Intellectual property rights must be observed by both parties
- Confidentiality agreements may be necessary
- Accurate and up to date records must be maintained (and shared where appropriate)
- Requirements may vary between companies, check what's needed

Market Research Process

Client to provide

or maintain as appropriate

- Contract – General Data Protection Regulation/Data Protection Act 2018 (GDPR/DPA) compliant
- Non-disclosure agreement (NDA)
- Objectives
- Relevant standard operating procedure (SOP) extracts
- Stimulus
- Project contacts
- Approval & maintain approval records
- Privacy notice (if required) – GDPR/DPA 2018 compliant
- Training requirements & competency certification
- Deadline and landmark delivery dates

Agency to provide

or maintain as appropriate

- Proposal or project outline
- Work order
- Recruitment script, screener, questionnaire, guide
- Details of any 3rd party data processors
- Consent form(s) and privacy notice – GDPR/DPA 2018 compliant
- Receipt of reimbursement form
- Observer agreement
- Client agreement to safeguard recordings
- Updated biographies of key project personnel
- Sub-contractor assessment (if required)
- Relevant SOP extracts
- Project timeline

Adverse Event Reporting

Client to provide

or maintain as appropriate

- List of Marketing Authorisation Holder (MAH)'s drugs
- AE/PC/SRS report form(s)
- Lawful basis for collecting personal data
- Reporting timeframe & frequency
- Pharmacovigilance (PV) contact details for questions & reporting
- Reconciliation form and deadline
- Quality control (QC) requirements (e.g. checking source data)
- Training & competency certification requirements
- Company training materials if necessary
- Format of tabulated reports
- Relevant SOP extracts
- AE/PC/SRS record keeping requirements

Agency to provide

or maintain as appropriate

- Confirmation or proof of AE /PC/SRS certification
- Training records (upon request)
- Completed AE/PC/SRS Reports
- Completed AE/PC/SRS reconciliation form
- QC feedback
- Records of AEs/PCs/SRSs reported (post fieldwork)
- Relevant SOP extracts
- Project timeline

Further Information

For further detail on all guidelines please see the BHBIA Legal & Ethical Guidelines for Healthcare Market Research at www.bhbia.org.uk

If you have any queries about this Quick Guide or the BHBIA Legal & Ethical Guidelines for Healthcare Market Research, please visit www.bhbia.org.uk and submit your query via 'My BHBIA' dashboard. Please note: this ad hoc advisory service is available to full BHBIA members only.

Disclaimer

This guidance is provided by the BHBIA for information purposes only and is not intended and should not be construed as regulatory or legal advice. It does not cover all legislative and regulatory requirements pertaining to Members and it is the responsibility of all Members to familiarise themselves with these.

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