

BACKGROUND

There remain some important unanswered questions for the market research industry following the introduction of GDPR. Quality and compliance are fundamental to the M3 Global Research approach, and many clients have asked us to share our viewpoint on these important topics.

In practical terms, we will look at each project on a case-by-case basis and make an informed decision to both help our clients manage risk and ensure the success of the overall research.

IDENTIFYING END CLIENTS IN ALL RESEARCH

Recently both the BHBIA and EphMRA have provided some guidance from the European Data Protection Board's (EDPB) Key Provisions subgroup, which was attended by all the major member state Data Protection Authorities (DPAs). The EDPB is the EU body in charge of the application of the GDPR. Both reported:

"We have been informed that the consensus amongst the EDPB group was that, where organisations are jointly determining the purposes and means of processing, they will be considered joint data controllers (in accordance with GDPR Article 26), regardless of whether one controller is only determining the purposes and the other only determining the means.

*The group was also in agreement that, in a joint controller scenario, where personal data are collected from the data subject, both controllers must be named when the data are obtained (in accordance with the requirements of GDPR Article 13(1)(a)). However, this is not formal guidance and further discussions are going to take place." **

While M3 cannot offer legal advice, we concur that **if** personal data is collected during the survey then this is indeed the case. However, the guidance says nothing about the more normal MR scenario where survey responses are anonymous and no personal data is collected as part of the survey. It is also silent on the scenario where an end client and MR agency jointly formulate a survey that does not collect personal data but the online survey host collects limited personal data (e.g. an IP address) for their own purpose, using their own means and without any direction from either the MR agency or end client.

While we do not believe it is likely to be necessary, if our client (and potentially their client) determine that they are data controllers or joint data controllers of personal data collected in a survey and wish to identify themselves then we will support this as long as they make it clear that M3 is not providing any of our members' personal data to be associated with the survey responses and remains committed to protecting their privacy.

On the other hand, if our clients believe they are not collecting any personal data, and therefore cannot be data controllers of it, then we will support their not being named until and unless further guidance points to the contrary.

IDENTIFYING END CLIENTS IN QUALITATIVE RESEARCH

Some countries in the EU (including Sweden, and we expect more countries to follow suit) have already taken the stance that audio files/video files are personal data. Remote live viewing counts as data processing which in turn means that, under GDPR rules, respondents need to be informed in advance which company will be viewing their data. This does not affect in-person viewing in a backroom through a one-way mirror, as this does not constitute a data transfer.

We are taking the cautious approach in assuming that all EU countries will take this stance, which does have an effect on live viewing by research sponsors, since their naming might potentially introduce research bias. It isn't possible to simply ask respondents to waive this

and inform them afterwards; it is a requirement for this naming to take place upfront for live remote viewing/listening.

The passing on of recordings to the sponsor can also take place with informed consent from respondents in place. In this case, the end client would need to be named after the interview is completed (as part of the consent) and before the recording is transferred.

Transcripts after the interviews can of course be provided in any case.

One option would be to blur the video (which is a service offered by FocusVision) but the audio would also need to be distorted; in this format the audio/video would cease to be personal data when neither picture nor voice are recognisable, and then live remote viewing could take place. We have queried with FocusVision regarding whether or not this is a service they will be offering in light of GDPR. We will also explore technological solutions to facilitate this.

With this in mind, the good news is that research sponsors would still be able to listen in to non-English interviews, when a research sponsor would only hear the interpreter and not the respondent him/herself.

ADVERSE EVENT REPORTING

The current process of adverse event (AE) reporting violates several tenants of GDPR and the consensus is that fieldwork companies like M3 Global Research will need to pass contact details of respondents directly to pharmacovigilance departments within the end client. This, amongst other things, ensures that the principles of data minimisation and privacy by design are respected.

In the absence of any standards, when M3 is asked to assist in passing contact details to pharmaceutical clients due to AEs reported during online studies the following applies:

1. M3 Global Research checks that the respondent agreed, in principle, to be recontacted in the case of an AE being identified (if necessary contacting the agency hosting the survey)
2. M3 will then contact the respondent in order to obtain their fully informed consent (naming the end client and informing them of their rights) to their details to be passed onto the pharmacovigilance department of the end client for the purpose of AE reporting
3. During this process, M3 will also confirm with the healthcare professional which contact details can be passed on. M3 needs this confirmed prior to passing on contact details, regardless of which consent was captured in the online link
4. M3's client can still report within 24 hrs any adverse events and the reporter's contact details will be provided at a later stage
5. For those who give their consent, we will provide respondents' contact details directly to the end client
6. M3 Global Research's direct client will provide their M3 project manager with the contact details of the end client and the reference number that should be used
7. After reporting the AE, M3 will ensure that our direct client will receive a copy of the receipt M3 has received from the end client.

* Source: <https://www.bhbia.org/latestnews/news/namingclient.aspx>