Dear Mrs Cooper, dear M. Tovey, dear M. Bruckner

I thank you for your letter with your report « Clinical Trial transparency : a guide for policy makers ». 

Inserm as a signatory of the WHO Joint statement on public disclosure of results from clinical trials is already committed to some relevant actions. This doesn’t appeared on the De Vito et al. paper because the authors have not been able to join us at the time of the article redaction. We have sent some important precisions three months ago and you will find them enclosed.

You will see that Inserm fully already some important commitments about studies registrations or final rapport summaries submissions. We are now beginning the most tricky actions such as deadline compliance or individual participant data sharing. We would like also, improve our internal and external communication about this paramount matter.

Sincerely yours.

Claire Giry
Acting Chairman and CEO
Inserm applies a transparency policy which is not yet formally drafted. This redaction is scheduled in the next weeks. The transparency policy will have to be approved by Inserm bodies. In addition, the Institute has scheduled to update the clinical research page on its website. Nevertheless, several concrete actions have already been put in place, other ones will be implemented according to modalities currently being defined, particularly in view of the constraints linked to the European regulation on personal data.

1. Registration of clinical trials with Inserm as sponsor: All clinical trials are registered on the international clinical trials website https://clinicaltrials.gov/ or on others at the request of some investigators or funders. The obligation of this registration is indicated to every investigators in regard of the Institute’s transparency policy and is subject to control in the context of internal audits conducted by Inserm’s promotion structure.

2. Sharing the results: The majority of clinical trials promoted by Inserm are published in peer-reviewed journals. The final report summaries are, as far as possible, deposited on the site on which the studies were reported. The obligation to obtain final report summaries from the investigator is included in the Institute’s transparency policy. The investigators are supported by Inserm’s promotion structure to provide the final report summary within one year after the closure. The submission of the final report summaries will be subject to control as part of the external audits conducted by Inserm’s promotion structure.

3. Sharing individual data: While Inserm as the developer owns the data of the studies, in the context of some multi-partnership protocols, the sharing of anonymous individual data can be planned and supervised by consortium agreements. Nevertheless, the overall policy of sharing individual data remains in the development phase.