Context
Clinical trials have entered into the era of public disclosure. Recent regulations, such as Policy 00701, implies public disclosure of clinical reports (mainly clinical overviews, clinical summaries, clinical study reports and some of their appendices). A consistent approach is therefore needed to allow data utility while preserving personal data confidentiality (low risk of re-identification).

Anonymisation method
Anonymisation of a CSR requires determination of 1/ the direct and quasi-identifiers (safe-Habor method), 2/ the required level of anonymisation, and 3/ the methodologies to be used (keeping in mind the need to have a balance between the clinical data utility and the risk of re-identification). Methodologies include removal/masking, generalisation and randomisation.

In this first step of public disclosure of clinical reports, removal/masking appears to be the easiest method. Each method can have different levels of utility depending on the data set. Experience and proactive data anonymisation will lead to an increase in the use of the other methods.

Challenges
In all cases, the anonymisation strategy (data to be anonymised, methods) must carefully take into account the specificities of the conducted studies (study risk level). A important step to be considered is pro-active writing: Strategies such as generalisation and aggregation can be used for the primary clinical study report to facilitate anonymisation.

Conclusion
Anonymisation of clinical reports is a challenging matter which will need constant fine-tuning by a multi-disciplinary team. Anticipation and pro-active writing may be key assets for that process.

References:
1 EMA policy External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use. Apr 2017.
2 Transcelerate Biopharma Inc. Protection of personal data in clinical document – A model approach.