

Vodeya: A Real Life Example of EMA Policy 0070 in Rare Disease

00:53:41 As this was a large package, how did you ensure that you meet the proposal submission timelines? Any best practices?

01:13:27 are there cost implications apart from the time

01:15:49 also - we have had a lot of push that we have to use DocuSign to move away from wet ink but but that leaves the doc with the Sig/date/ and IP address - is there any alternative that

01:20:18 Could you also comment on the redaction of metadata of each document or is that obvious?

01:25:12 Hi all, I have been involved in several Policy 0070 projects and the presentation has reflected the process very well. Thank you!!

01:37:19 I would like to also mention there are also transparency requirements for Clinical trials according to the EU Regulation, to take into account when writing the protocol or CSR to be used in other regulatory procedures outside scope of Policy 0070