

Steve Kopko

From: Steve Kopko
Sent: Friday, October 16, 2020 11:47 AM
To: COADataStandards; Helena Sviglin
Cc: Steve Kopko; Dana Booth; Diane Corey
Subject: **Request Input ** FDA QRS subteam members experience with the BPRS instrument
Attachments: BPRS 1962 original reference paper.pdf; BPRS 1988 ref article.pdf; BPRS 1988 Version Annotated CRF.pdf

We would appreciate your input on the FDA submission experience in reviewing the BPRS instrument based on the difference we have found in the public domain versions of the BPRS CRF. Attached are the original 1962 BPRS and 1988 BPRS reference papers by the author that we have been using, along with the CRF. We are implementing the more current 1988 version. We were about to send the supplement for your internal review when the following issue was identified.

The 1988 reference paper includes the list of items and responses on page 99 of the paper. The list of responses on this page does not include the response of 0 = "Not assessed", which is on the CRF we received from the person who requested the BPRS instrument as a standard and are using for the supplement. We have found this CRF on numerous websites, so it is probably being used by sponsors. As with other public domain instruments there may evolve with multiple versions of the instrument as it is used over time. The 18 item version seems to be commonly used and was the original request.

We would appreciate your input regarding the FDA experience in reviewing the BPRS instrument in historic submissions. Was the additional 0 = "Not assessed" included on those BPRS CRFs? It seems to be an improvement in adding another level of granularity to the responses of interest. Do you have a preference on the inclusion of this responses before we send the supplement? We wanted to address this to avoid it coming up as a comment during the review. Please let us know if you would like to meet on this topic, once you have researched it.

Thanks for your assistance on this topic,
Steve, Dana, & Diane

Steve Kopko | CDISC Subject Matter Expert Consultant



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401 West 15th Street, Suite 800 | Austin, TX 78701

Mobile +1.484.868.0251

cdisc.org

