

2020 QRS Supplement Update

14-Jul-20

<b>QRS Supplement Type</b>	<b># Published</b>	<b>QRS Development Status</b>	<b>Ongoing</b>
Questionnaires	3		
Functional Tests	1		
Clinical Classifications	2		
<b>Total</b>	<b>6</b>		

  

<b>QRS Supplement Development Step</b>	<b>Number</b>
<b>Initial Development</b>	17
<b>Developed Awaiting General Issues Resolution</b>	2
<b>QRS Team Review</b>	6
<b>CDISC Internal Review</b>	3 Ready in July
<b>In FDA First IR</b>	0
<b>Awaiting FDA Internal Review</b>	2 MMSE & MMSE-2 on hold until res
<b>Post FDA IR Comment Resolution</b>	3 NSCLC-SAQ V1.0, SMDDS V1.0, & P
<b>Between CDISC IR and PR - Comment Resolution</b>	17
<b>Copy Editing prior to Public Review</b>	20 PEDSQOL 1-18 set for PR in July
<b>In Public Review</b>	0
<b>Between CDISC PR and Publication - Comment Resolution</b>	8
<b>Copy Editing prior to Publication</b>	0
<b>Copy Editing prior FDA Quick Review</b>	0
<b>Final FDA Quick Review prior to Publishing</b>	4 DMD FT supplements & Annotated
<b>Published in 2020</b>	6
<b>Total</b>	<b>88</b>

ponse from PAR

ASI

l CRFs in comment resolution