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To access this measure, please follow these steps:

1. Fill out request form (pages 2-5 of this document)
2. Email the form to: [IQVIA\\_COAs@iqvia.com](mailto:IQVIA_COAs@iqvia.com)

In addition:

- A Cronos licensing agreement with updated “Terms and Conditions” will be required for all licensees.
- Translation development and screen reviews will be managed by IQVIA (i.e., translation by 3rd party vendors will no longer be permitted)

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Both English and Spanish CRFs are available.

## REQUEST FORM

| 1          | Specify type of request   | <input type="checkbox"/> New Instrument License<br><input type="checkbox"/> Amendment Instrument License<br><input type="checkbox"/> Instrument Scoring (IQVIA to score the completed instruments)  |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
|------------|---|---|------------|---------|----------|--|--|--|--|--|--|--|--|--|--|--|--|
| 1a         | Specify instrument for which request in row 1 above is needed and Translations Needed<br><i>(please enter all that apply)</i> | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Instrument</th> <th style="width: 30%;">Country</th> <th style="width: 30%;">Language</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>   | Instrument | Country | Language |  |  |  |  |  |  |  |  |  |  |  |  |
| Instrument | Country   | Language  |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
|            |   |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
|            |   |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
|            |   |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
|            |   |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
| 2          | Complete Name of Project Sponsor<br><i>(please enter Full Legal Name)</i>   |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
| 2a         | Sponsor Company Classification <i>(please select one)</i>   | <input type="checkbox"/> Pharmaceutical Company<br><input type="checkbox"/> CRO<br><input type="checkbox"/> For-profit Hospital<br><input type="checkbox"/> For-profit Healthcare System<br><input type="checkbox"/> Other for-profit company type <i>(please write in):</i><br><hr style="border: 0; border-top: 1px solid blue; margin: 2px 0;"/> <input type="checkbox"/> Non-profit Hospital<br><input type="checkbox"/> Other non-profit company type <i>(please write in):</i><br><hr style="border: 0; border-top: 1px solid blue; margin: 2px 0;"/> <input type="checkbox"/> Government<br><input type="checkbox"/> Registered Charity<br><input type="checkbox"/> Academic University<br><input type="checkbox"/> Other <i>(please write in):</i><br><hr style="border: 0; border-top: 1px solid blue; margin: 2px 0;"/> |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
| 3          | Project Funding Source<br><i>(please enter Full Legal Name)</i>   |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
| 3a         | Project Funding Source Classification<br><i>(please select one)</i>   | <input type="checkbox"/> Pharmaceutical Company<br><input type="checkbox"/> CRO<br><input type="checkbox"/> For-profit Hospital<br><input type="checkbox"/> For-profit Healthcare System<br><input type="checkbox"/> Other for-profit company type <i>(please write in):</i><br><hr style="border: 0; border-top: 1px solid blue; margin: 2px 0;"/> <input type="checkbox"/> Non-profit Hospital<br><input type="checkbox"/> Other non-profit company type <i>(please write in):</i><br><hr style="border: 0; border-top: 1px solid blue; margin: 2px 0;"/> <input type="checkbox"/> Government<br><input type="checkbox"/> Registered Charity<br><input type="checkbox"/> Academic University<br><input type="checkbox"/> Other <i>(please write in):</i> _____  |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |
| 4          | Full Legal Name of Company Signing the Agreement <i>(please note the</i>  |   |            |         |          |  |  |  |  |  |  |  |  |  |  |  |  |

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|   |   |   |
|---|---|---|
|   | <i>company signing the agreement and paying for the invoice must be the same)</i>   |   |
| 5 | Names of Any Third Parties Accessing/Administering/Scoring the selected instrument <i>(please list all applicable and enter Full Legal Name for each one)</i>                                 |   |
| 6 | Full Legal Name of Company Responsible for Compliance with Legislation on Post-marketing Safety / Pharmacovigilance and Clinical Research Guidelines (e.g., from the IRB/EC) for this Project |   |
| 7 | Full Legal Name of Company that is the Marketing Authorization Holder for the Project (MOH) and is the Applicant  |   |
| 8 | Project Classification <i>(please select one)</i>   | <p><b>Research:</b></p> <p><input type="checkbox"/> Phase I Clinical Trial</p> <p><input type="checkbox"/> Phase II Clinical Trial</p> <p><input type="checkbox"/> Phase III Clinical Trial</p> <p><input type="checkbox"/> Phase IV Clinical</p> <p><input type="checkbox"/> Observational (real-world) Project</p> <p><input type="checkbox"/> Registry</p> <p><input type="checkbox"/> Student Project</p> <p><input type="checkbox"/> Other <i>(please write in):</i> _____</p> <p><b>Healthcare Provider Use:</b></p> <p><input type="checkbox"/> Routine Care</p> <p><input type="checkbox"/> Other <i>(please write in):</i> _____</p> |

|     |  |  |
|-----|--|--|
| 9   | Project Disease Area   | <input type="checkbox"/> Acute Care<br><input type="checkbox"/> Allergy/Immunology<br><input type="checkbox"/> Cardiovascular<br><input type="checkbox"/> Dermatology<br><input type="checkbox"/> Endocrinology<br><input type="checkbox"/> Gastrointestinal<br><input type="checkbox"/> Hematology<br><input type="checkbox"/> Hepatology<br><input type="checkbox"/> Infectious Disease<br><input type="checkbox"/> Medical Genetics<br><input type="checkbox"/> Nephrology<br><input type="checkbox"/> Neurology<br><input type="checkbox"/> Oncology<br><input type="checkbox"/> Ophthalmology<br><input type="checkbox"/> Orthopedics<br><input type="checkbox"/> Psychiatry<br><input type="checkbox"/> Respiratory<br><input type="checkbox"/> Rheumatology<br><input type="checkbox"/> Transplantation<br><input type="checkbox"/> Women's Health/Sexual Health<br><input type="checkbox"/> Other <i>(please write in):</i><br><hr/> |
| 10  | Project Primary objective  |  |
| 11  | Project Secondary objective  |  |
| 12  | Project Exploratory objective  |  |
| 13  | Planned study endpoint for the selected instrument<br><i>(please select one)</i>   | <input type="checkbox"/> Primary Endpoint<br><input type="checkbox"/> Secondary Endpoint<br><input type="checkbox"/> Exploratory Endpoint<br><input type="checkbox"/> Other <i>(please write in):</i><br><hr/>   |
| 14  | Is there a study objective to assess the psychometric properties of the selected instrument?   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No  |
| 15  | Number of Sites  |  |
| 16  | Number of Subjects   |  |
| 17  | Age of project population  |  |
| 18  | Mode of Administration<br><i>(please mark all that apply)</i>  | <input type="checkbox"/> Paper<br><input type="checkbox"/> Electronic<br><input type="checkbox"/> Phone<br><input type="checkbox"/> Interactive Voice Response ("IVR")<br><input type="checkbox"/> Other <i>(please write in):</i> <hr/>   |
| 18a | If Mode of Administration is Electronic, on what type of device may the selected instrument be accessed? <i>(please mark all that apply)</i> | <input type="checkbox"/> Computer<br><input type="checkbox"/> Tablet <i>(specify all models, e.g. TABLET IPAD AIR 2):</i><br><hr/> <input type="checkbox"/> Smartphone <i>(specify all models, e.g. IPHONE 6):</i>   |

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|     |   | <input type="checkbox"/> BYOD <i>(please write in which devices will be used e.g. Tablet, Smartphones, etc.):</i> _____<br><input type="checkbox"/> Other <i>(please write in):</i> _____   |
| 18b | If Mode of Administration is Electronic, who is providing the device for questionnaire completion?  | <input type="checkbox"/> Patient<br><input type="checkbox"/> Project Sponsor<br><input type="checkbox"/> Other <i>(please write in):</i> _____  |
| 18c | If Mode of Administration is Electronic, how is the selected instrument programmed?   | <input type="checkbox"/> eCOA Platform<br><i>(please write Full Name):</i> _____<br><input type="checkbox"/> Web Browser<br><input type="checkbox"/> Other <i>(please write in):</i> _____  |
| 19  | Name of eCOA Vendor <i>(only if Mode of Administration = Electronic)</i><br><i>(please mark all that apply – Please also enter Full Legal Name of the company migrating the paper COA to the electronic format if different from eCOA Vendor)</i> | <input type="checkbox"/> Clario (ERT)<br><input type="checkbox"/> IQVIA<br><input type="checkbox"/> Medidata Solutions<br><input type="checkbox"/> Signant Health<br><input type="checkbox"/> YPrime<br><input type="checkbox"/> Other <i>(please write in):</i> _____  |
| 20  | Are you interested in IQVIA's eCOA platform? <i>(only if Mode of Administration = Electronic)</i>   |   |
| 21  | Number of administrations per subject   |   |
| 22  | Expected First Patient In Date  |   |
| 23  | Project End Date  |   |
| 24  | Have you contracted IQVIA to run any aspects of this project? If so, for which services have you contracted IQVIA (Planning, Execution/Data Collection, and/or Reporting)? <i>Please indicate all</i>   |   |
| 25  | How did you learn about the instrument?   | <input type="checkbox"/> Use in previous study of ours<br><input type="checkbox"/> Literature<br><input type="checkbox"/> PubMed<br><input type="checkbox"/> Other <i>(please specify):</i> _____<br><input type="checkbox"/> IQVIA Website<br><input type="checkbox"/> Word of mouth <i>(please specify):</i> _____<br><input type="checkbox"/> Other <i>(please specify):</i> _____ |
| 26  | Will the COA data from this project be used in a labeling claim?  | <input type="checkbox"/> Yes<br>Please specify Agency to which the labeling claim will be submitted:<br><input type="checkbox"/> FDA<br><input type="checkbox"/> EMA<br><input type="checkbox"/> Other<br><input type="checkbox"/> No   |