Meeting Minutes

Meeting purpose	**Internal Ad Hoc Call (CMDL Requirement)**
Date	**30 August 2023**
Start & End Time	**10:00 AM to 11:30 AM (Philippine Standard Time)**
Location	**Online (via MS Teams)**
PCRP BOD/Facilitators (3)	Al Ryan Baniqued (Parexel)– PCPR Auditor Beverly Red De Leon (Zuellig) – Organizational Development Committee Head Rhys Jansen Pavon (Parexel) – P.R.O.
Attendees (18)	Grace Mendoza – Past PCRP President, Honorary Member Jennifer Arellano (Novotech) – Past PCRP President, Honorary Member Maria Rosario Mislang (PPD) – PCRP Ways & Means Committee Head Maricel Alcoriza – IQVIA Claire Reyes – IQVIA Geraldine Guerina – Parexel John Eric Hilario – Pfizer Jennifer Nisperos – CMIC Lourdes Pecundo – Novotech Ma. Joy De Rama – Unilab Marissa Laureta – Tigermed Mary Anne Osorio – Fortrea Rosary Reyes – Syneos Rodmar Pulido – PiVOT Ross Ronsayro – Roche
Meeting Materials	**Position Paper to FDA-P CDRR and CDRRHR 30 June 2023** PCRP Position Paper on the CMDL directive **FDA Administrative Order (AO) No.: 2018-0002** AO 2018-0002 Guidelines Governing **CDRRHR's Citizen Charter** FDA Citizens Charter CDRRHR CMDL_poste **FDA Circular No.: 2020-001-A** FDA-Circular-No.2020-001-A.pdf
Pre-meeting Survey Questions 1. Do you or your company have	**Sponsor A:**

any experience with CDML application? If so, what were the queries or action items raised upon filing of CMDL application and what was the turnaround time from submission to acknowledgement up to approval?	Yes. We were required to submit a CMDL application after receiving an NOD. Turnaround time for processing of CMDL is 20 business days. Then this will be forwarded to Center for Device. Once cleared, this will be reflected in the import license issued by CRS. No clear timelines after application is forwarded to Center for Device. **Sponsor B:** Yes. The exact use of the medical device in the study. b) EC certificates or Declaration of conformity for each medical device. c) Disposal process of electronic medical devices (digital thermometers, etc). d) Signed commercial invoice to be used in the actual shipment indicating the quantity, invoice number, date of purchase. **CRO A:** Yes Queries: Copy of CPR/N from country of origin, Correction on application form and letter **CRO B:** Yes 14Jun2023: We received the first query from CRS requesting for CMDL application via CDRRHR. Several pushback and back-and-forth's were done with both CRS and CDRRHR. The following were confirmed as medical devices requiring CMDL: Needles, Needle Holder, Syringes, Body Thermometers 14Jul2023: 8 CMDL Applications, one for each device were lodged. **Per the Citizen's charter it should only take 11 days for CDRRHR to release the approval/comments. Unlike with CRS where NODs are communicated directly via email, CDRRHR documents their queries via a wet-inked letter that will be scanned and sent via email. 26Jul2023: IL Approval was received. Clarification with CRS was sent to ask if Supplies requiring CMDL can be shipped since IL is already at hand. CRS responded that "it is advised that the CMDL should be attached and prepared together with the Import License Approval upon importation of items. For your reference, approval documents may also be checked during routine inspections." 11Aug2023: NODs were received for each 8 Application. Queries were mostly for the following: • Missing tick boxes on the application form • Certificate of product registration document needs to come from a foreign RA (MSDS or Technical Data Sheet is insufficient)

	• Comments on packing list • Quantity justification **We tried several times to push back the contents of the Lab Kits to be exempted as we have received feedback for our other studies that these are no longer required being an IVD. However, our request was denied. 29Aug2023: Planned submission of response to NOD. **Around 26Jul2023, we have received several NODs requiring CMDL for our other studies: 2 IL Amendments and 2 more initial submissions. We tried pushing back the contents of the lab kits being tagged as medical devices citing that, by definition, these are In Vitro Diagnostic Devices and are not covered by A.O No. 2018-002, CRS agreed and accepted our pushback. IP Ancillary supplies, Obvious medical devices (ECG Machine, Electrodes, Vitalographs) are still required and will be applied for CMDL. We have received the IL amendment approval shortly after. **CRO C:** Yes Certificate to Foreign Government (CFG) document was not accepted as an equivalent document of the Certificate of Product Registration (CPR), which is one of the requirements for CMDL application. Specific invoice numbers for the shipment are also required for the application, as we have been informed by PFDA that this will also be reflected on the CMDL. Please refer to the TAT below for one of our CMDL applications: Submission - 03Aug Received NOD (Notice of Deficiency) - 16Aug Pending approval as of date.
Pre-meeting Survey Questions 2. With this mandate to apply for CMDL on top of Import License for non-medical device clinical trials, what do you think are the anticipated challenges that could impact our industry?	**CRO B:** Certificate of Product Registration or any documentation attesting to the safety of the medical device is required but this may not be readily available. **Sponsor B:** Delay on the importation of the ancillary medical devices needed for the study leading to increased chances of protocol deviation and delays in enrollment. **CRO D:** Slower timelines **CRO A:** • Longer CT timelines; • Possible delay in shipment of CT supplies;

	• Impact to study milestones; • Lower chance for PHL to be selected as participating country in clinical trials **CRO C:** Delay in obtaining the appropriate approvals, as EC approvals must first be in place before applying for CMDL. It would also be very time-consuming and costly, especially for studies that do not have designated depots in the country, in which each shipment will require CMDL. CDRRHR also requires specific invoice numbers for the shipments that will require CMDL; this invoice number will only be obtained once the shipment has been ordered by the Study Sponsor.
Pre-meeting Survey Questions 3. What are the questions you would like to raise to P-FDA regarding this new mandate, Administrative Order (AO) No.: 2018-0002 Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements, and/or CDRRHR's Citizen's Charter?	**Sponsor A:** Can we submit the CMDL application in parallel with the import license application to CRS? Will the CMDL application cover one lab kit including its components? Validity of CMDL? **Sponsor B:** • Can the FDA revert to the previous process of streamlined CT application and IL application? • Can CDRRHR provide a CMDL that covers all the quantity needed for the entire study and require a quarterly importation notification (similar to CRS process) instead of requiring a CMDL submission for each shipment? **CRO A:** For FDA to clarify scope of CMDL in the context of actual clinical trials in the PHL **CRO C:** • FDA should provide a list of clinical trial medical devices that would require CMDL application and which are exempted. • CRS and CDRRHR should coordinate and consolidate their requirements.
Meeting Highlights	• Recent mandate from FDA to apply for CMDL separately from Import License application for ancillary supplies that will be used to support drug/vaccine clinical trial, thus increasing Site Start-up Timeline in the Philippines. PCRP members concur that the CMDL requirement is important but the purpose should be directed for those who plan to introduce the medical device for commercial use and should not be applicable for non-medical device vaccine and drug trials. • There is a dilemma on exactly when to apply for CMDL. If we apply for CMDL for all ancillary supplies at the same time with Import License, there is a possibility that CDRRHR will issue an NOD confirming certain items that are not classified as medical device. This would in turn require the company to process an IL amendment to include those

	items not under CDRRHR's purview. On the other hand, if we wait for FDA to issue NOD on the items that needs a CMDL, then this will effectively increase the timeline from submission to approval before medical devices can be imported into the country because NOD is issued weeks after filing the initial clinical trial application and would mean that the overall RA submission to RA approval timeline may go beyond the prescribed timeline of AO 2020-0010: 60 days. Currently, CDRRHR is the only agency that is able to identify which among the ancillary supplies used in a drug/vaccine trial will require a CMDL application. Assessment whether a specific item is classified as a medical device is undisclosed to us and seemingly inconsistent. • High workload and resources required for CMDL Application from both applicant and approver's end. 1 CMDL pertains to only 1 medical device item. CMDL is also unique per shipment because the invoice number is reflected in the CMDL. Application per medical device item will entail collection of multiple required documents. Some documentary requirements will take time to obtain after requesting it. One example is the Manufacturing Certificate. It is often the case that the logistics team of the company will source the ancillary supplies and it can be from different sources. Hence it will take time for global logistics team to request a copy of these documents from the manufacturer. • Timeline from submission to issuance of CMDL can stretch more than 20 working days. Experience from Member Companies that CDRRHR sometimes takes a long time to reply. - Parexel submitted in Jul 2023 but no approval as of this meeting. - IQVIA submitted on Jun 2023 but no approval as of this meeting. • Head of IQVIA Philippines have secured an audience with FDA of the Philippines and is scheduled to have the meeting soon, and will take that opportunity to request if PCRP can have another meeting with them as well to further discuss the CMDL issue at the industry level. • PCRP's point person for the CMDL issue will be Al Ryan Baniqued. PCRP member should email to Al and cc PCRP BOD so that we can collate the information.
Real Impact of CMDL Requirement to the Industry	**Sponsor B** Out of 19 CMDL applications, they received 15 NODs and 4 disapprovals

	(meaning the items are not considered medical device needing CMDL). In the 15 NODs, some requirements were very difficult to comply, such as submission of Declaration of Conformity or Manufacturing Certificate. Certificate of Compliance is not acceptable. Because of the long timeline for CMDL approval, Sponsor B made the decision to no longer recruit more participants for their study when the items for importation had already exceeded the amounts approved in their initial IL. **CRO B** Several NODs were received requiring CMDL for a number of studies resulting to 2 IL Amendments and 2 more initial submissions. Attempted to push back and explained that contents of the lab kits being tagged as medical devices are by definition "In Vitro Diagnostic Devices" which are not covered by A.O No. 2018-002, CRS agreed and accepted the appeal. IP ancillary supplies, Obvious medical devices (ECG Machine, Electrodes, Vitalographs) are still required and will be applied for CMDL. IL amendment approval was received shortly after the appeal was granted.
Proposed Workaround and Action Plans	**Short Term** • If a Notice of Deficiency (NOD) is received from CDRRHR requesting for the REC approval, provide proof of REC submission/application instead. Sponsor B has experience with this and CDRRHR accepted their response. • If there are electronic medical devices involved, include in the CMDL application an explanation on how this will be disposed afterwards. • When FDA issues NOD stating that In Vitro Diagnostic Medical Devices should require CMDL, provide feedback that these devices are not within the scope of CDRRHR AO No. 2018-002. IVDs should be included in IL and not require CMDL. • Each company has to proactively request (in advance of the forecasted/planned receipt of RA approval letter/IL) for documents from global the required in the submission of CMDL application. • To collect detailed experience from member companies on CMDL NODs and how they were resolved. Create an active file that will serve as a FAQ log for member companies to use as reference when dealing with CMDL application. • Reach out again to FDA (CDRR and CDRRHR) with a follow-up position paper including the actual experiences/real scenarios of member companies and seek a dialogue/meeting/roundtable discussion with them. To also acknowledge FDA on issues that were resolved in the position paper to recognize their efforts. **Long Term** • Establish a routine catch-up call (quarterly, semi annually or annually) with key stakeholders in FDA (e.g. Dr. Iris Tagaro) so that they are aware of the current challenges faced by the industry. • If FDA insists on requiring CMDL application for ancillary supplies used in non-medical device trials, PCRP to request to be included in

	consultation meetings to create a comprehensive list of medical devices requiring CMDL application. • Follow-up on the roadmap of PCPR BOD 2023-2025 and to generate annual report and share with key stakeholders so that they become aware of the developments and challenges in our industry and have room for collaboration where both roadmaps meet/align.