



Singapore Healthcare
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Clinical Research Material Notification (CRM-N) Pre-Submission Review for Device Development Project in SingHealth Medical Technology Office (MTO)

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Introduction

In 2016, the Health Sciences Authority (HSA) introduced the Clinical Research Material (CRM) regulations, which govern the import and supply of therapeutic or medicinal products and medical devices used on human subjects in regulated clinical trials and unregulated clinical research. CRM Notification (CRM-N) is a process of notifying HSA of the import or supply of CRM in situations of applicable exception to the requirement for the various dealers' licenses and product registration.

We have established a decision tool for the Principal Investigator(s) (PIs) involved in device development projects, in the determination of lead party responsible for the proper filing of CRM-N to HSA prior to commencement of clinical trial. The developed easy guide aims to empower PI(s) in the self-identification and assessment of lead party responsible for CRM-N filing so as to comply with HSA Medical Device Regulations.

Method

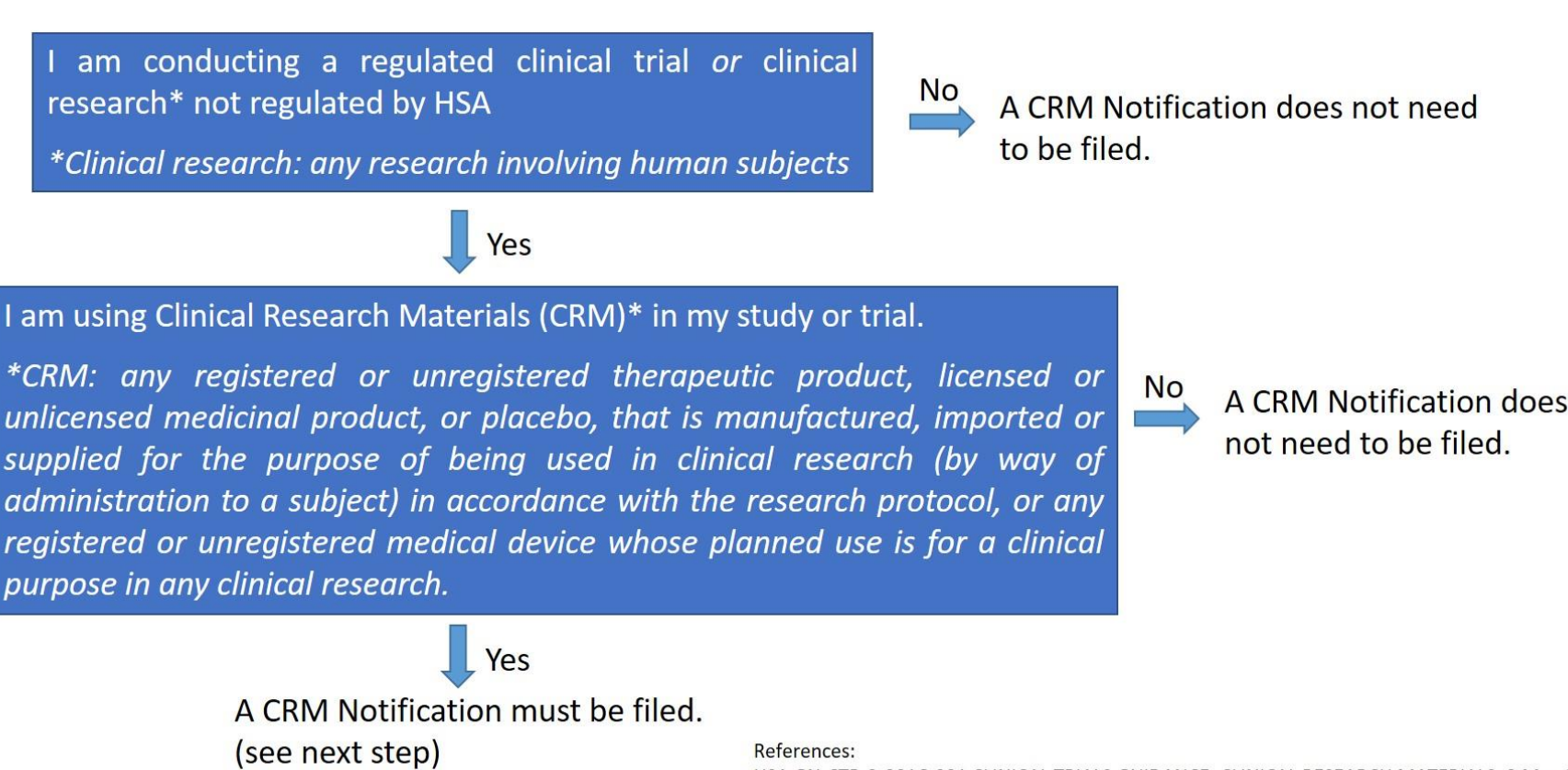


Following the EZ Guide: 4 simple steps

1

Determine if a
CRM-N is required

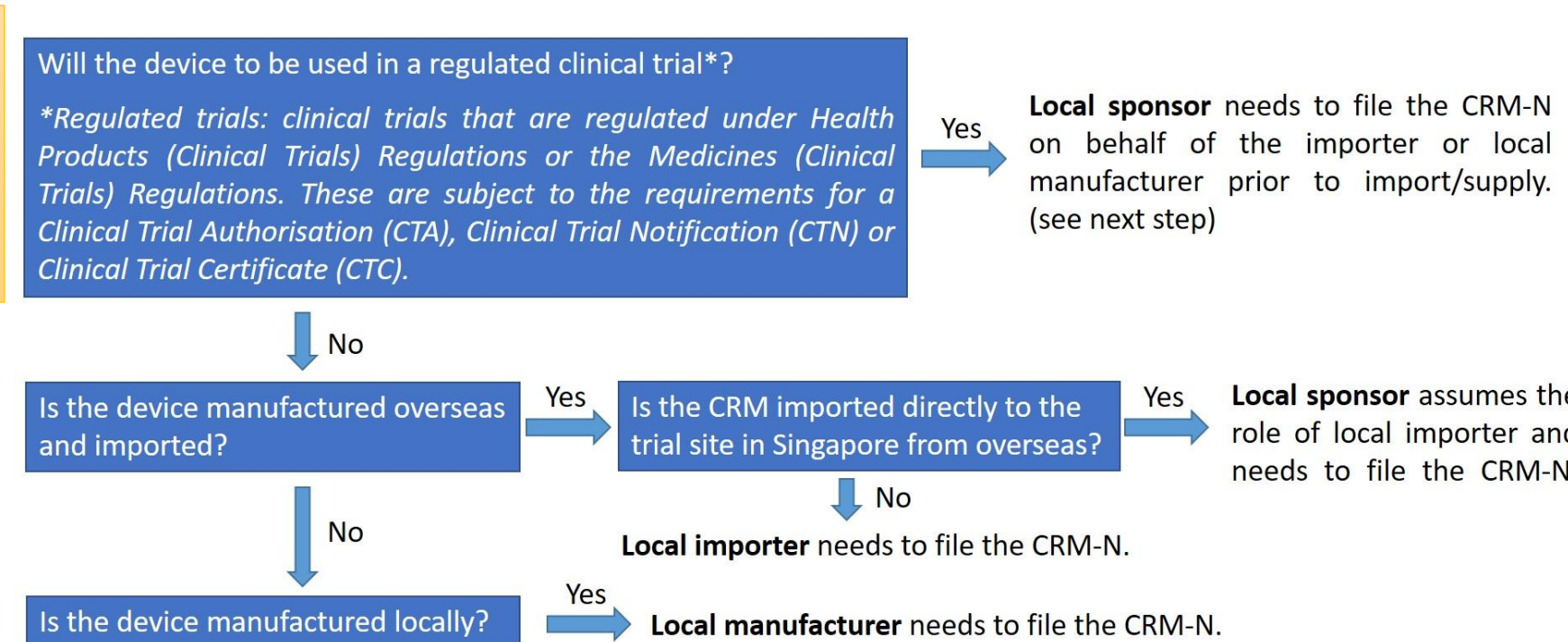
Must a CRM Notification (CRM-N) Be Filed?



2

Determine who
should file CRM-N

Who Must File the CRM-N for a Medical Device?



3

Understand who
takes the lead to
file CRM-N

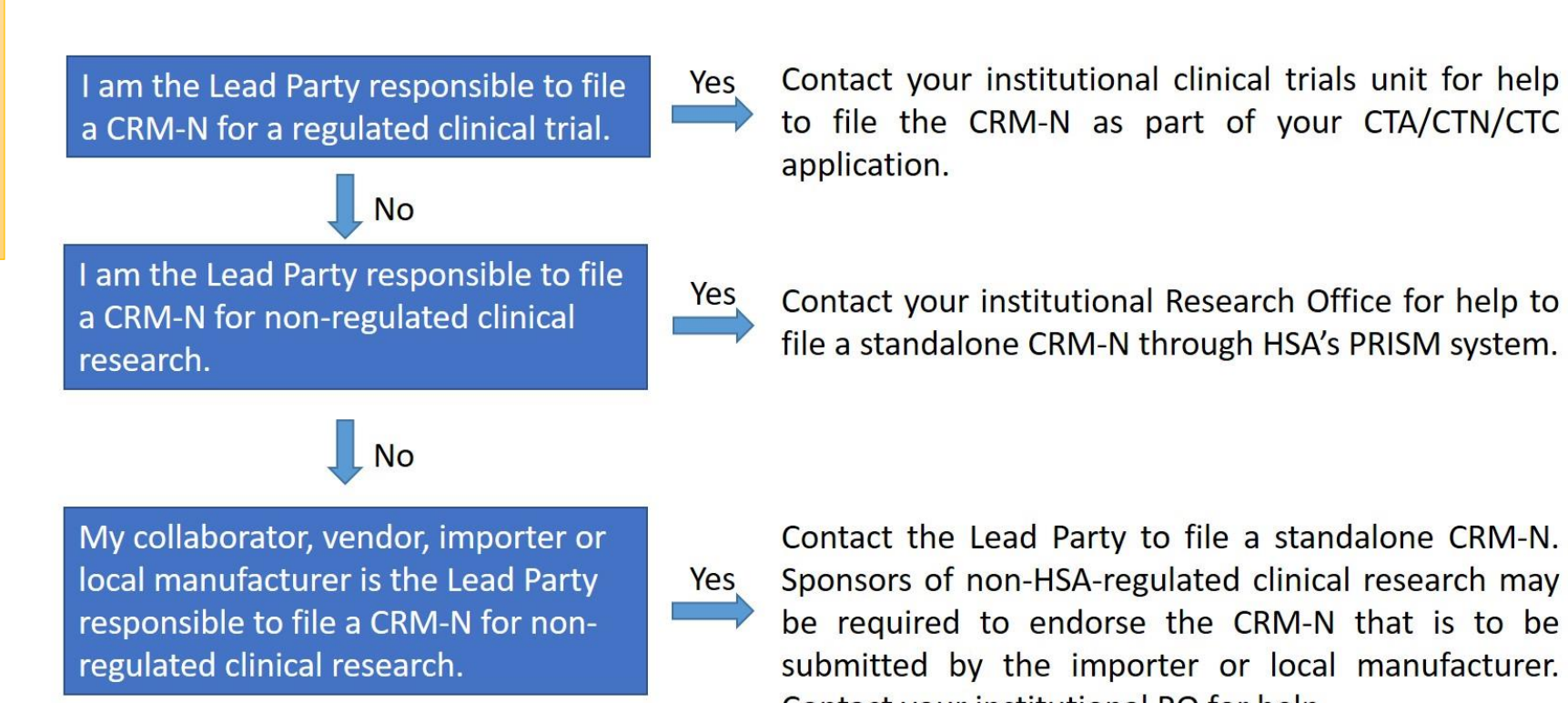
What is My Role?



4

Understand what
to do next

What is the Next Step to File a CRM-N?



A **CRM notification acknowledgement** will be generated and sent to sponsor, importer and manufacturer. It remains valid for 1 year for unregulated clinical research, or throughout duration of clinical trial i.e. until "last-patient-last-visit" LPLV for regulated clinical trials.

Result

We used the developed self-assessment matrix to evaluate the CRM-N needful on 3 internal projects prior to Institutional Review Board (IRB) submission. The developed guide was able to provide advice and support to PI(s) in the identification of the lead party for CRM-N compliance.

Conclusion

The identification and assessment of CRM-N leads in multi-parties device development and validation projects may indeed be complex. A well-defined, and transparent tool would be useful in ensuring timely application of CRM-N to HSA.

