

Tips for PMDA consultation

■Keys

- Before you do anything, you had better think you need approval from PMDA.
 - →Even if you hire regulatory consultants, you need to discuss with PMDA anyway.
- PMDA consultation is not “actual” consultation.
 - PMDA consultation meeting is the place where you confirm whether your plan is acceptable by PMDA or not. →When you meet with PMDA, you have concrete plan backed with reasonable data and rationale.
- Meetings are done in Japanese.

■Recommendation

- If you have secured MAH, let them handle regulatory matters.
- Approach “We have planed this way, and we think this is reasonable. Is this acceptable to you?”
- If you are startup/SME, we recommend to use RS consultation (cheaper).
- Bring a Japanese speaking person with you.

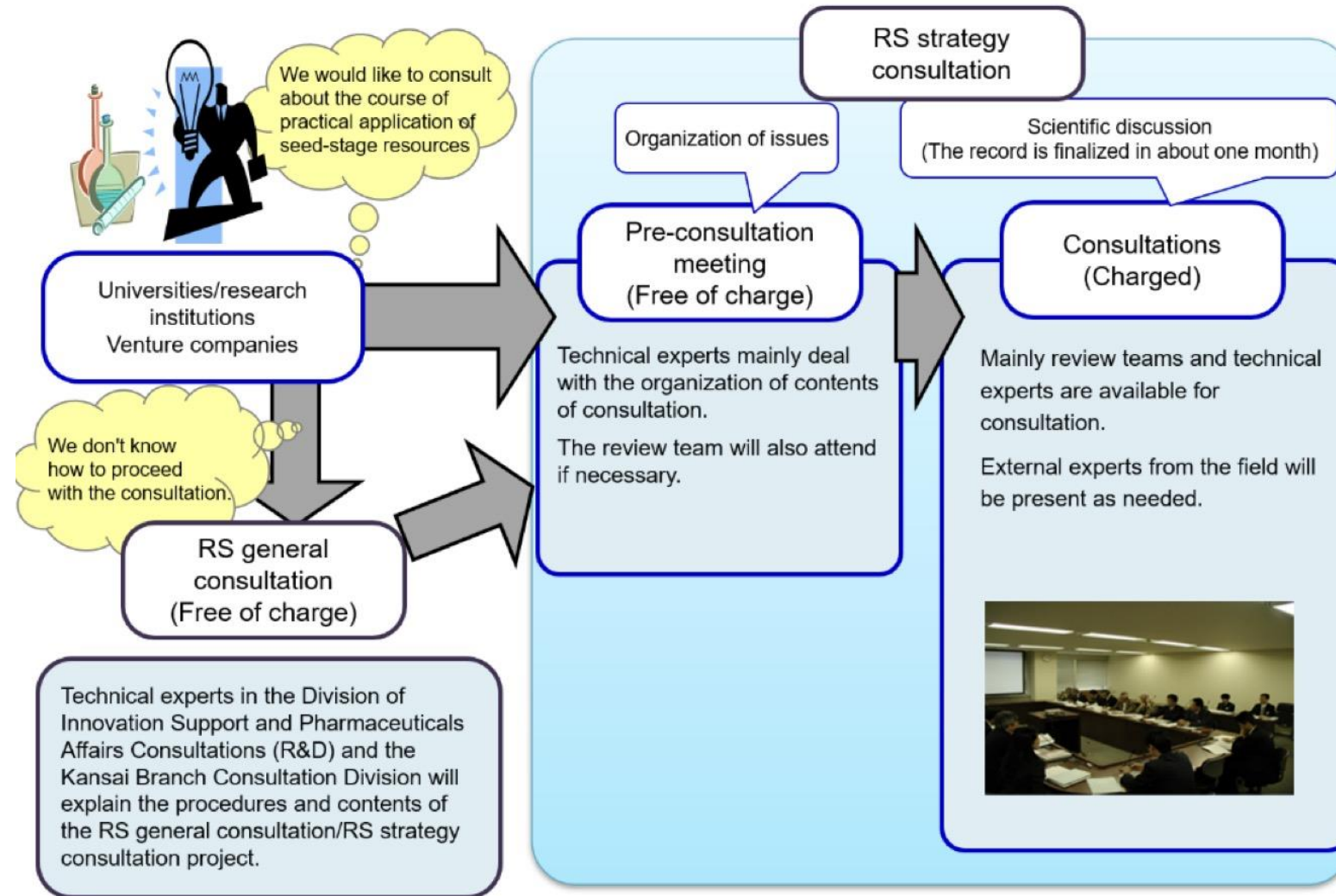
■General Consultation

- If you are unsure about what to do, go to RS general consultation first.
- Only general consultations can be done in English.

PMDA RS Consultations

- RS consultation; Regulatory Science consultation
 - Must to check
 - <https://www.pmda.go.jp/english/review-services/consultations/0002.html>
- Comprehensive Guide to RS Consultation
 - Must to check
 - <https://www.pmda.go.jp/files/000268545.pdf>
- Designed for academia/startups
 - A lot cheaper than the ordinary process, when qualified
- Only general consultation can be done in English.

RS Consultation Procedure



<https://www.pmda.go.jp/files/000268545.pdf>

Regulatory Authorities in Japan

MHLW

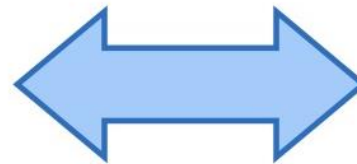
(Ministry of Health, Labour and Welfare)

- Final Authorization of applications
- Publishing Guidelines
- Supervising PMDA Activities

PMDA

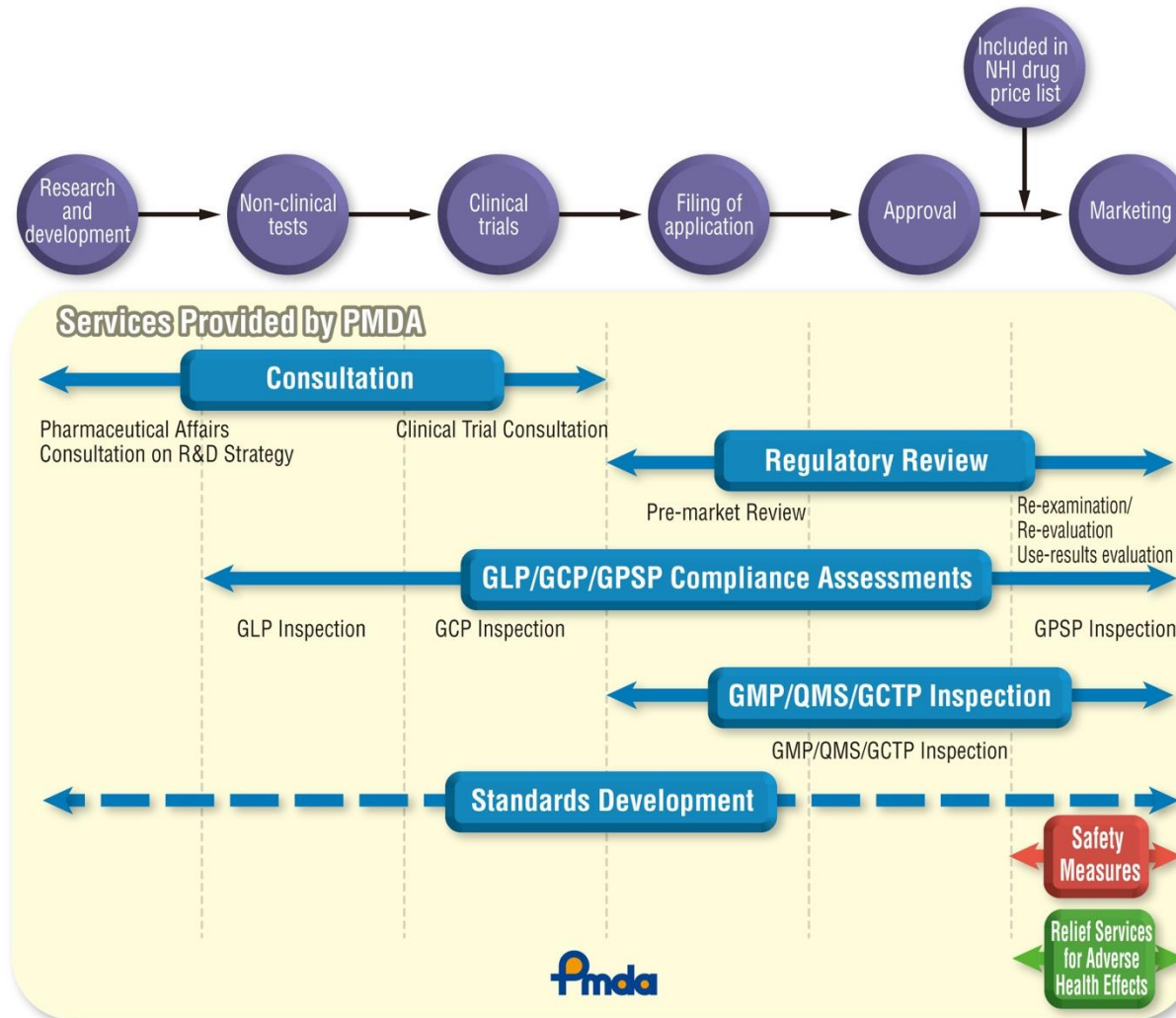
(Pharmaceuticals and Medical Devices Agency)

- Scientific Review
- Consultation on Clinical Trials etc.



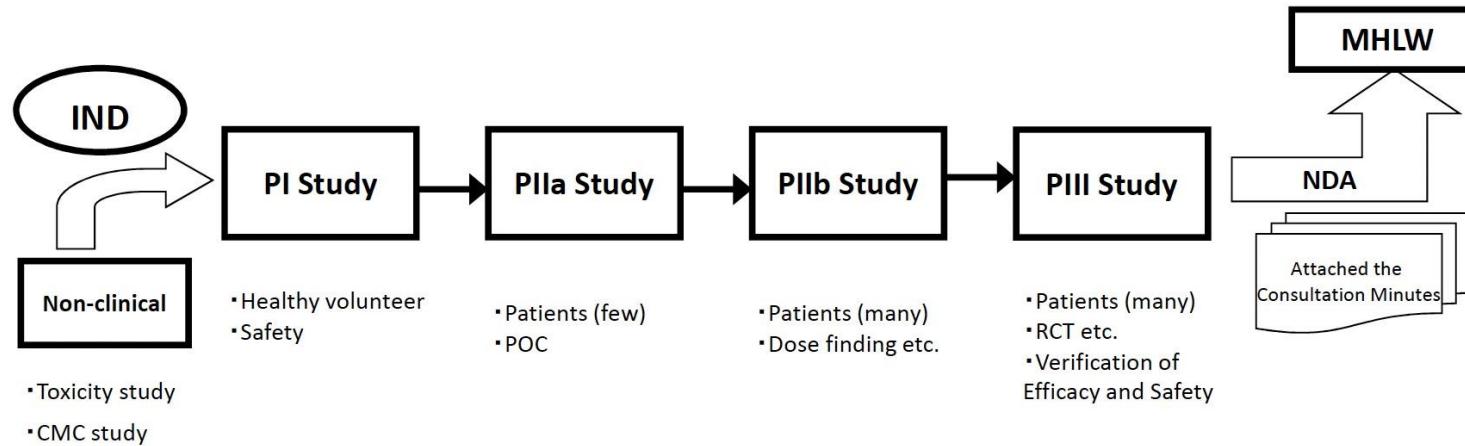
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Outline of reviews by PMDA

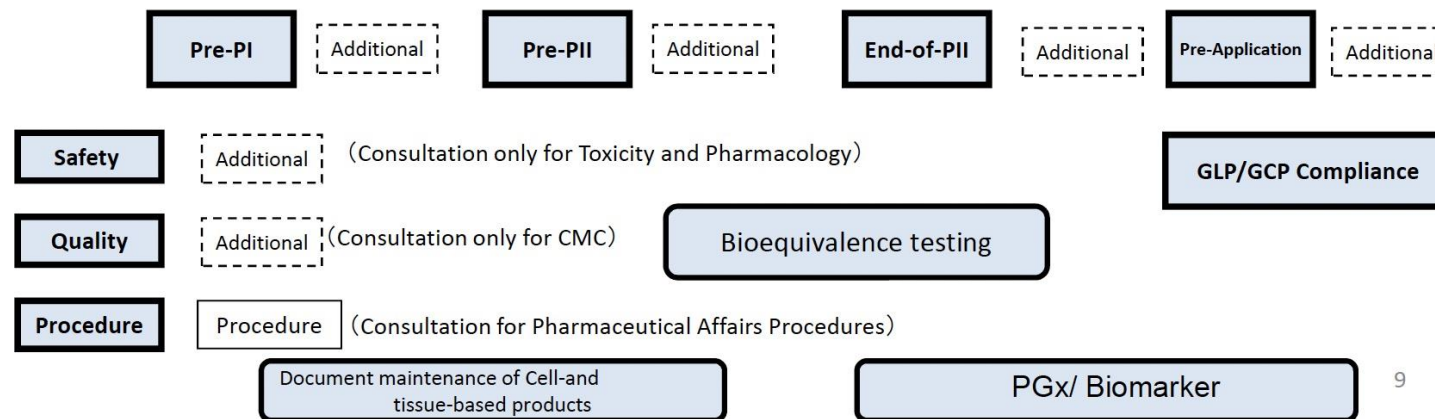


Source: <https://www.pmda.go.jp/English/review-services/outline/0001.html>

Clinical trial consultation System at PMDA



[Clinical trial consultation System at PMDA]



Source: PMDA