Compliance Check & Validation of Applications with an agreed PIP

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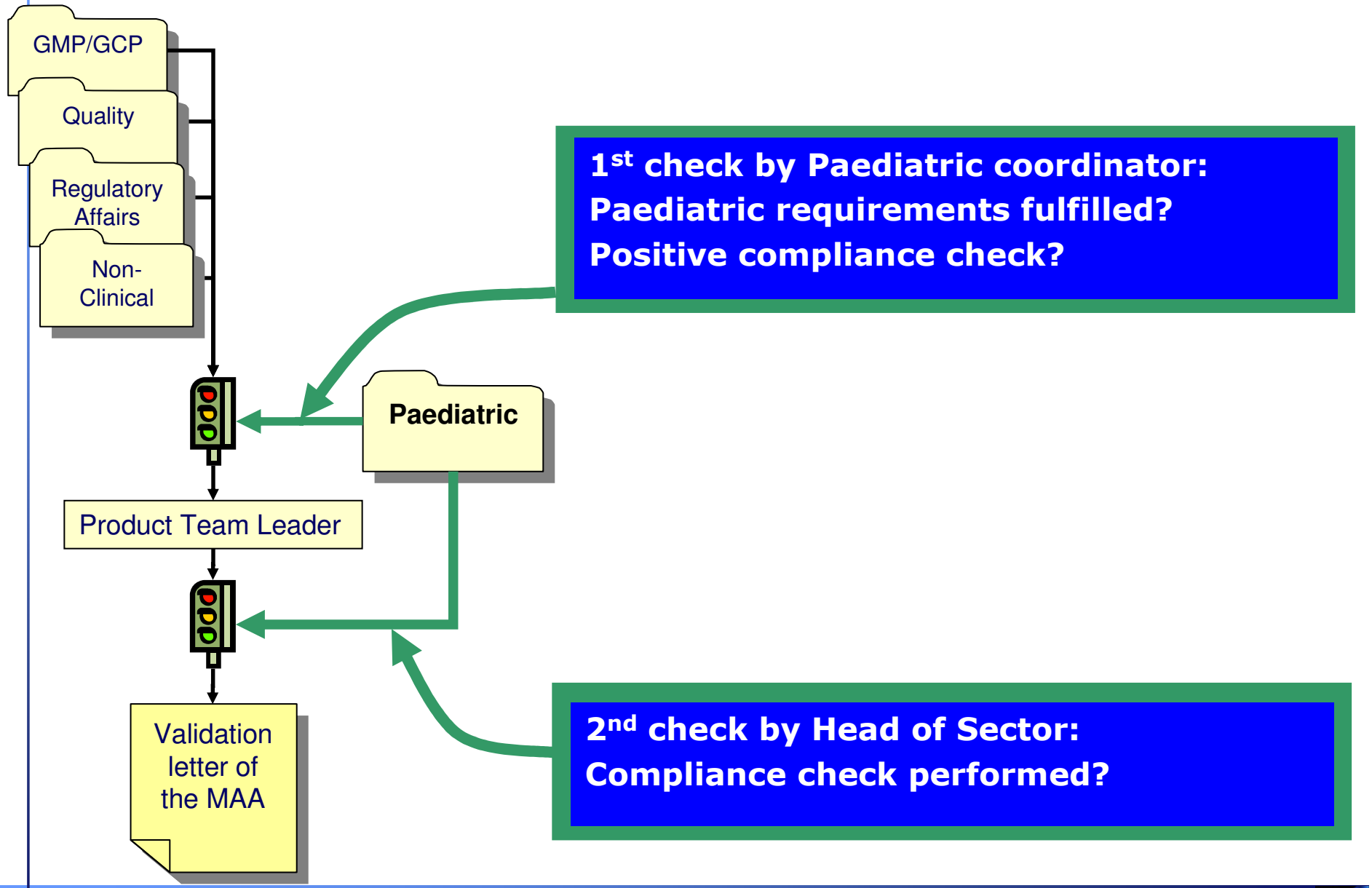
Compliance Check & Validation of Applications with an agreed PIP

1) Compliance and Validation

2) Compliance Check Procedure

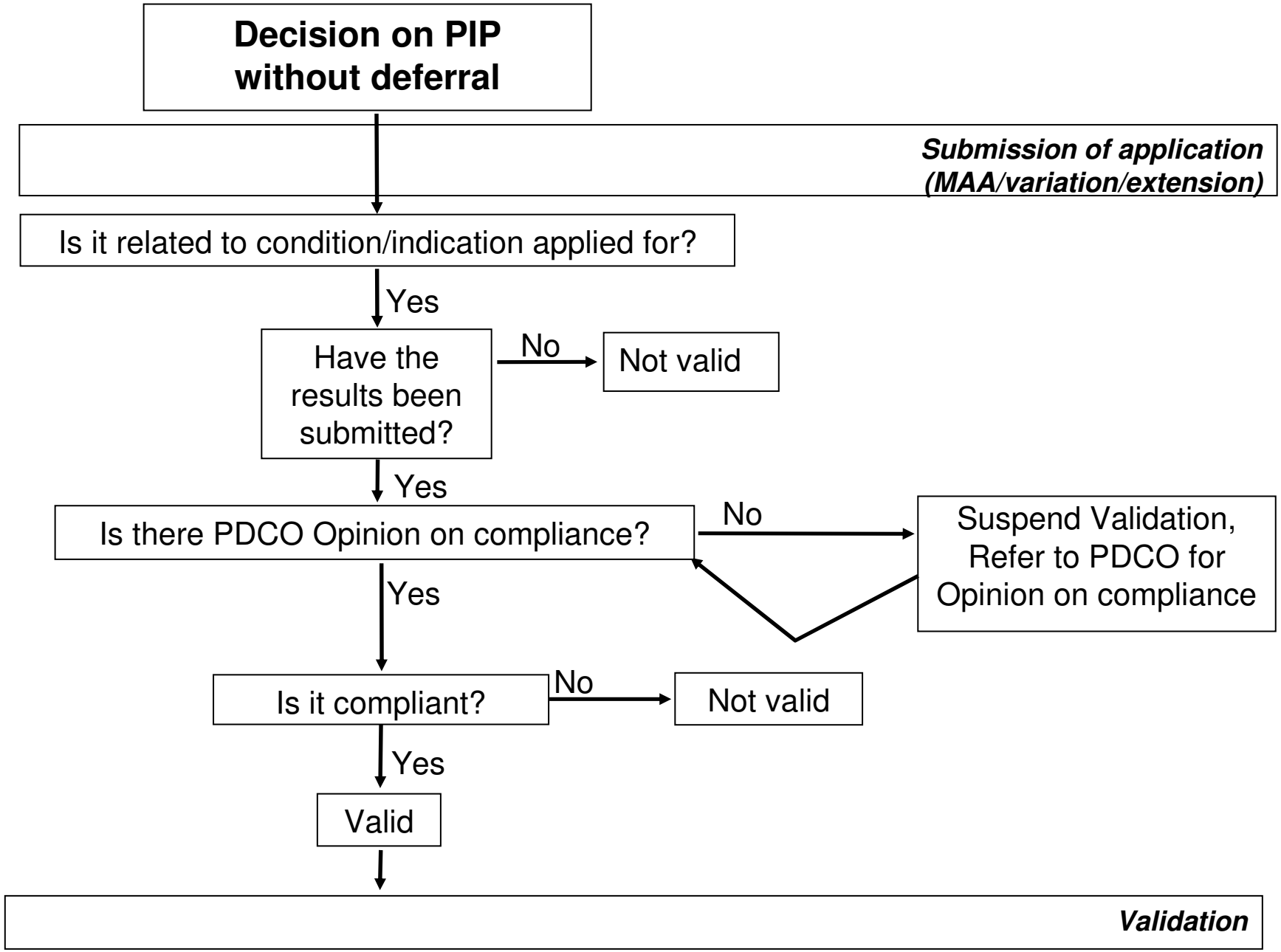
3) Points to Consider

1) Compliance and Validation



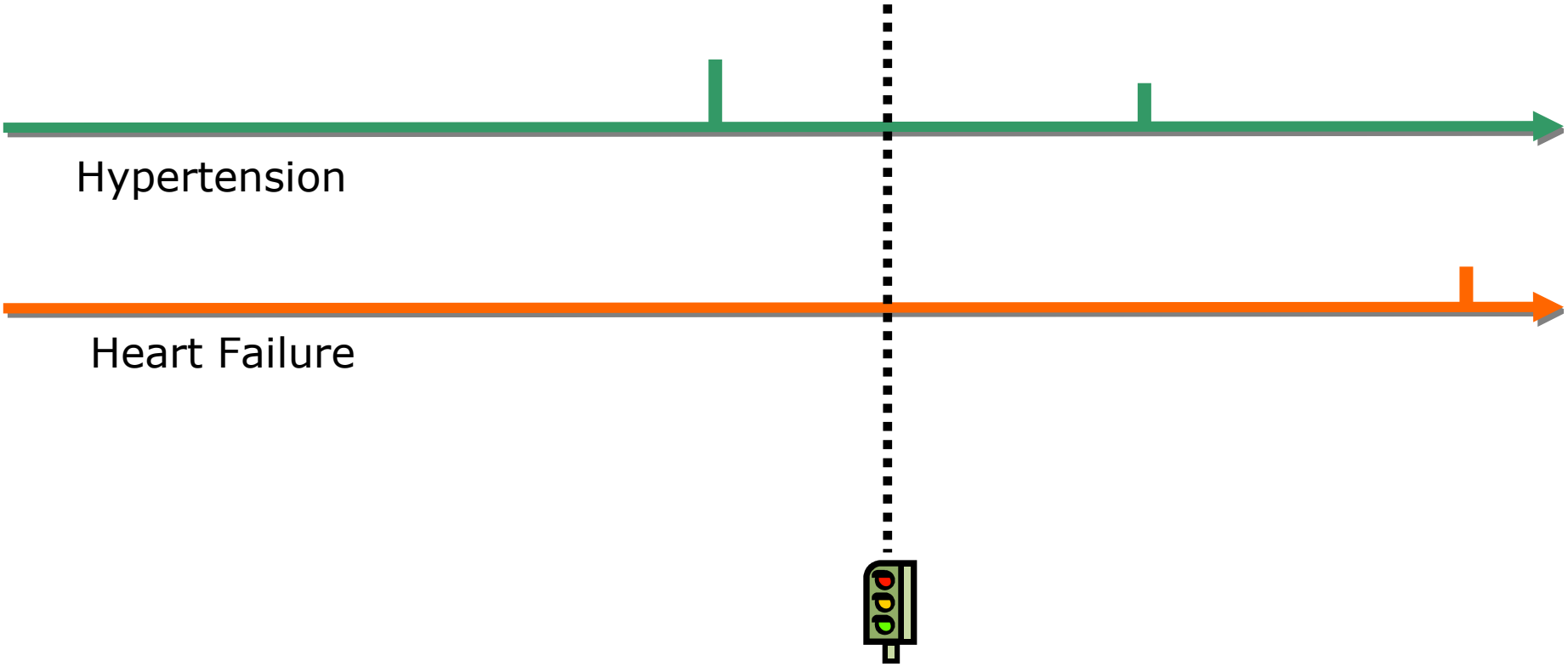
2) Compliance Check Procedure

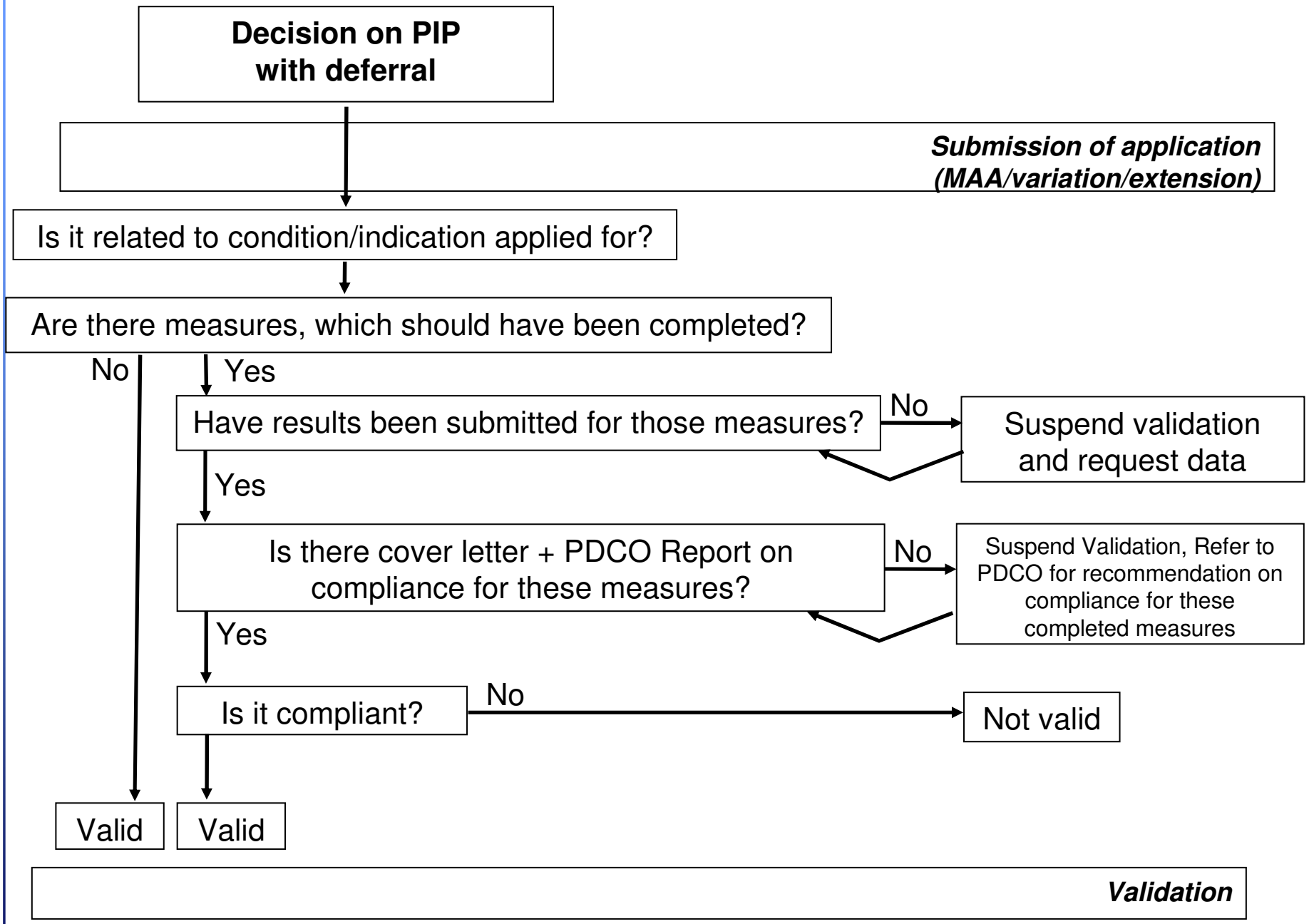
Based on:	Applicant's full study report decision's key binding elements
Involvement of:	Same Paediatric Coordinator and Rapporteur
Compliance: Check	***≠ assessment***
Judged as:	'yes' or 'no' on key binding elements NO negotiation, NO clock-stop, NO re-examination

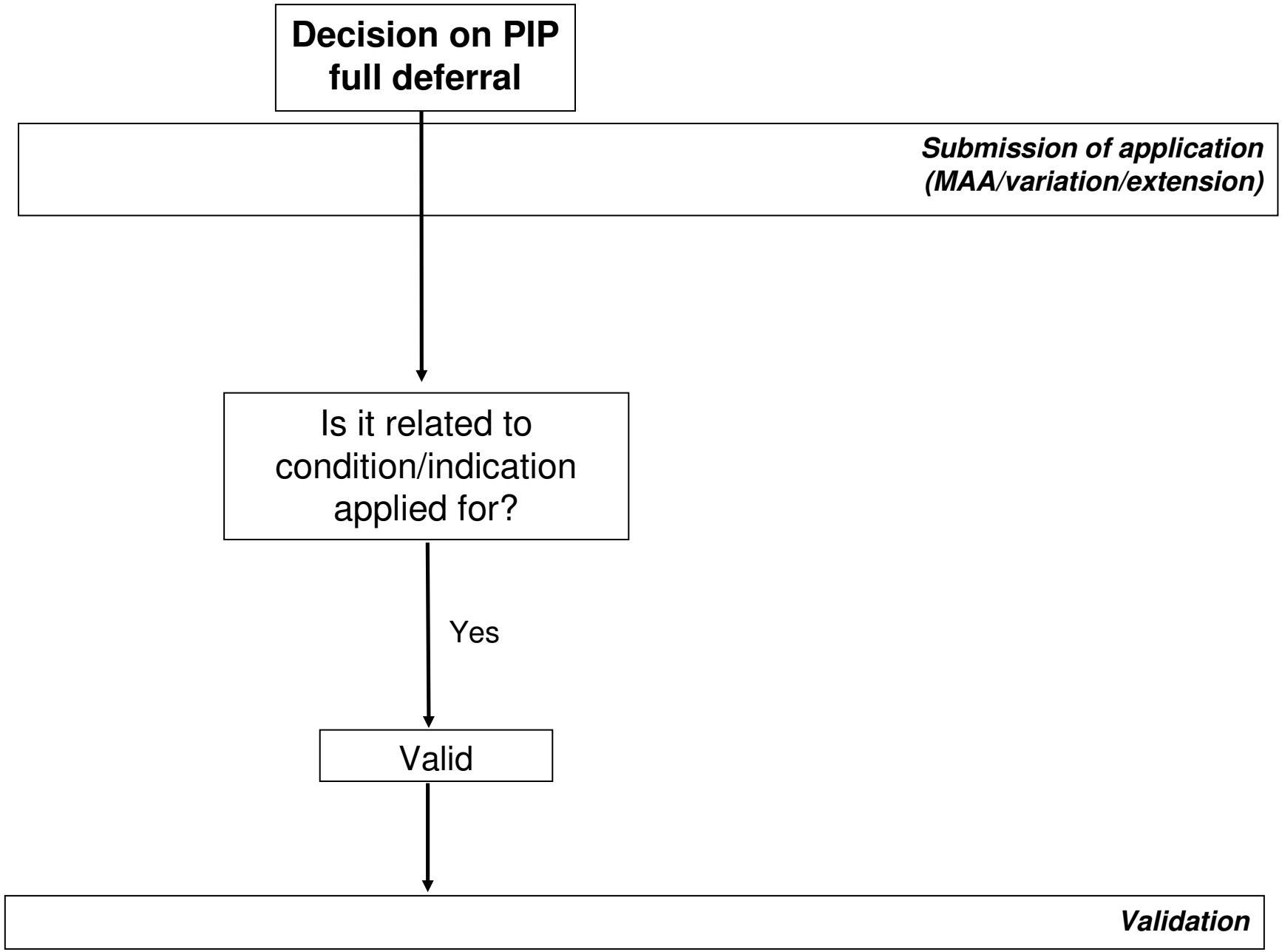

Decision on PIP without deferral
Submission of application (MAA/variation/extension)
Is it related to condition/indication applied for?
Yes
Have the results been submitted?
No
Not valid
Yes
Is there PDCO Opinion on compliance?
No
Suspend Validation, Refer to PDCO for Opinion on compliance
Yes
Is it compliant?
No
Not valid
Yes
Valid
Validation

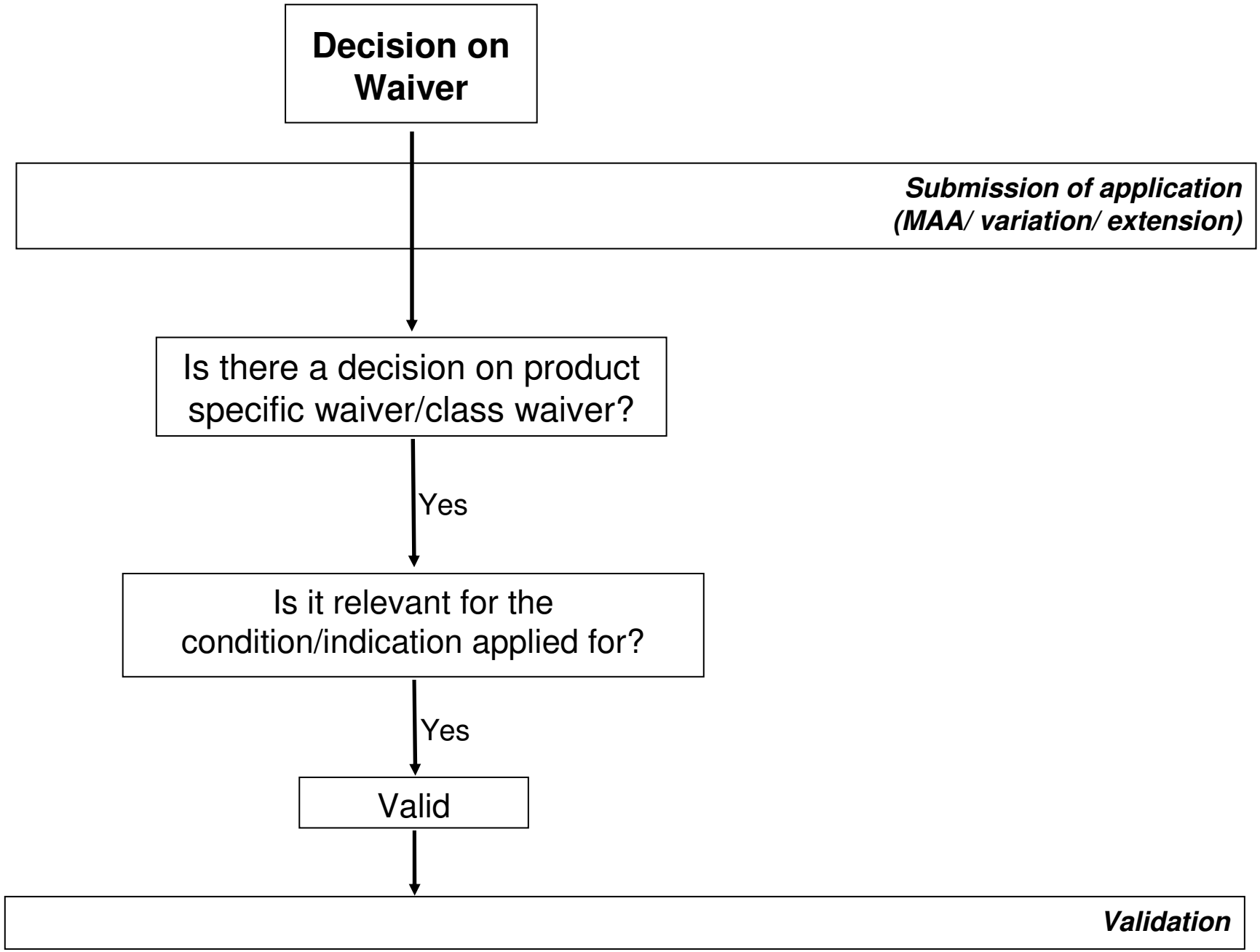
2) Compliance Check Procedure

- Hypertension Study 1 to be completed by **Sept. 2008**
- Hypertension Study 2 to be completed by **Dec. 2009**
- Heart failure Study to be completed by **Dec. 2010**




Decision on PIP with deferral
Submission of application (MAA/variation/extension)
Is it related to condition/indication applied for?
Are there measures, which should have been completed?
No
Yes
Have results been submitted for those measures?
No
Suspend validation and request data
Yes
Is there cover letter + PDCO Report on compliance for these measures?
No
Suspend Validation, Refer to PDCO for recommendation on compliance for these completed measures
Yes
Is it compliant?
No
Not valid
Valid
Valid
Validation


Decision on PIP full deferral
Submission of application (MAA/variation/extension)
Is it related to condition/indication applied for?
Yes
Valid
Validation


Decision on Waiver
Submission of application (MAA/ variation/ extension)
Is there a decision on product specific waiver/class waiver?
Yes
Is it relevant for the condition/indication applied for?
Yes
Valid
Validation

3) Lessons learned

key binding elements	final study report
Patients per subgroup 700 350 350 700 300 150 150	 619 305 314 618 291 147 144
Primary endpoint a, b	Primary endpoint a Secondary endpoint b
Multi-centre	Single-centre
750 + 750 patients enrolled	1002 + 618 patients enrolled

3) Lessons learned

- **Most compliance checks were requested before the submission of the application**
- **No postponement of the conclusion on validation of the marketing authorisation**
- **For PIP-application with completed study(ies), ensure to provide the latest info**
- **Company to check carefully the key-elements at time of opinion**
- **Inform PDCO on data affecting the ongoing development irrespective of whether adults or paediatric related**
- **Anticipate PIP modification to avoid postponing the validation**
- **Paediatric development and compliance check should now be an integral part of the product development and be anticipated in the timelines of the product development to plan MAA, variation, extension submission**
  -> being compliant is a requirement for validation