

**SI304: Amgen-Sponsored
Expanded Lab Data Collection for
FDA Submission**

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Why?

- Short term objective is to gather data needed to support Amgen's FDA submission.
- Ultimate objective is to improve dosing for future patients.

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What data will be collected?

- Post-baseline labs:
 - Hematologic: ANC, Platelets, Hgb
 - Hepatic: AST, ALT, total bilirubin
 - Renal: creatinine, measured creatinine clearance, calculated creatinine clearance

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At what interval?

- Every cycle for first 12 cycles, then every year until progression, at time of progression, and at regular follow-up visits.

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Scope

- Protocol to be amended
- New eCRF to be created
- Data to be retrospectively submitted for all patients with follow-up
- Extra funds will be made available
- Memo explaining details will be provided
- No clinical monitor visits!

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Questions?

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