

Trial Closure Letters

GCIIG Harmonization Ops Committee

TRIAL CLOSURE LETTERS

WHEN WOULD WE SEND?

- Premature closure
 - positive results
 - negative results
 - toxicity/safety issues
 - funding issues
 - lack of interest in study agents or modality
 - drug shortage
 - lack of accrual

TRIAL CLOSURE LETTERS

WHEN WOULD WE SEND?

- Planned Completion
 - positive results
 - negative results
 - unblinding results

TRIAL CLOSURE LETTERS

WHO GETS THEM?

- Investigators
- Support staff-nurses, CRA's , research team
- Patients
- Public
- Local IRB, regulatory agencies

TRIAL CLOSURE LETTERS CONTENT

- Trial results
- Procedures for orderly termination
- Effect on patient's follow-up schedule
- Subsequent treatment plans
- Unblinding results