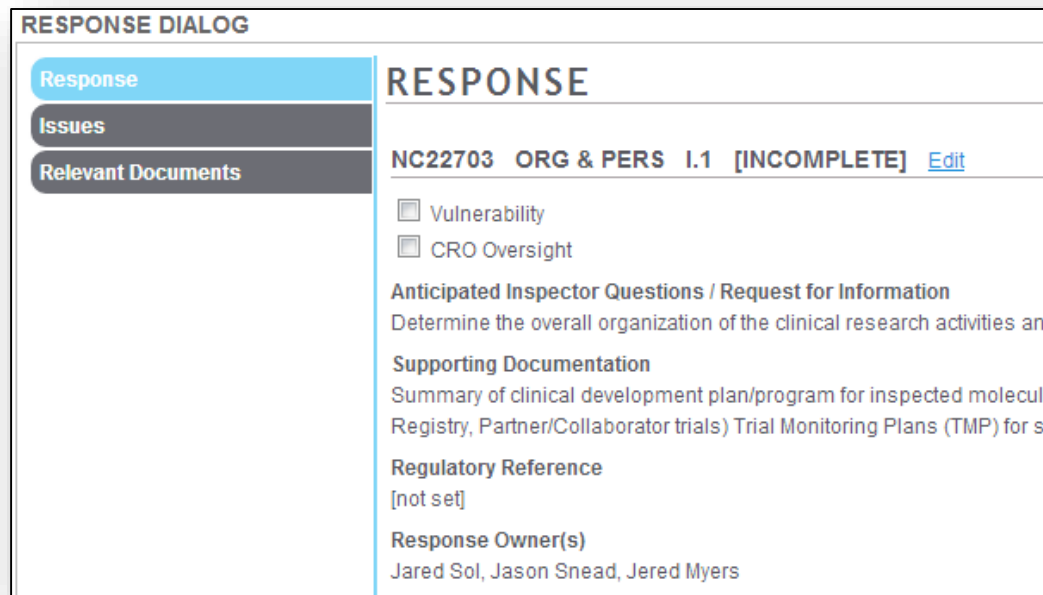


Response Dialog Menu

Record Inspection Vulnerability

This reference guide is an overview of how to **Record Inspection Vulnerabilities** within the **Response Dialog Menu**. These areas are covered within this document:

- ✓ Record inspection vulnerability



RESPONSE DIALOG

Response
Issues
Relevant Documents

RESPONSE

NC22703 ORG & PERS I.1 [INCOMPLETE] [Edit](#)

Vulnerability
 CRO Oversight

Anticipated Inspector Questions / Request for Information
Determine the overall organization of the clinical research activities and

Supporting Documentation
Summary of clinical development plan/program for inspected molecule
Registry, Partner/Collaborator trials) Trial Monitoring Plans (TMP) for se

Regulatory Reference
[not set]

Response Owner(s)
Jared Sol, Jason Snead, Jered Myers

Record Inspection Vulnerability

Record Inspection Vulnerability

1. Select **Vulnerability** (if appropriate).
2. Select **Vulnerability** type.
3. Click **Save Changes**.

RESPONSE

NC22703 ORG & PERS I.1 [Vulnerability Type Unknown ▼]

Vulnerability

CRO Oversight

Vulnerability Type Unknown ▼

- Study Level Vulnerability
- Systemic Vulnerability
- Both Vulnerability Types
- Vulnerability Type Unknown

RESPONSE

NC22703 ORG & PERS I.5 [Study Level Vulnerability ▼] [Edit](#)

Vulnerability

CRO Oversight

Anticipated Inspector Questions / Request for Information
(3) Determine who is responsible for final evaluations and decisions in reviewing S

Supporting Documentation
gcp_sop003277 RO-GNE: Clinical Trial Serious Adverse Events gcp_sop003277 R
Events gcp_spt002098 RO-GNE: Submission of Drug Safety Reports

Regulatory Reference
[not set]

Response Owner(s)
John Janzen

COMPLIANCE NOTES [Update Notes](#)

Save Changes