

# An analysis of data changes in response to real-time protocol violation (PV) alerts in an Electronic Data Capture (EDC) system.



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# What is a real-time protocol violation (PV) alert?



- **Pre-programmed rule in an electronic data capture system**
- **Triggers when a CRF is saved and the data deviates from what is allowed by the protocol**

# Benefits of PV alerts



- **Block ineligible subjects from randomization**
- **Immediate user retraining**
- **Capture reasons for violations**
- **Automated reporting of protocol violations**

# PV alert example: exclusion criteria



History of chronic liver disease.

No

Yes

Unknown

History of chronic liver disease.

No

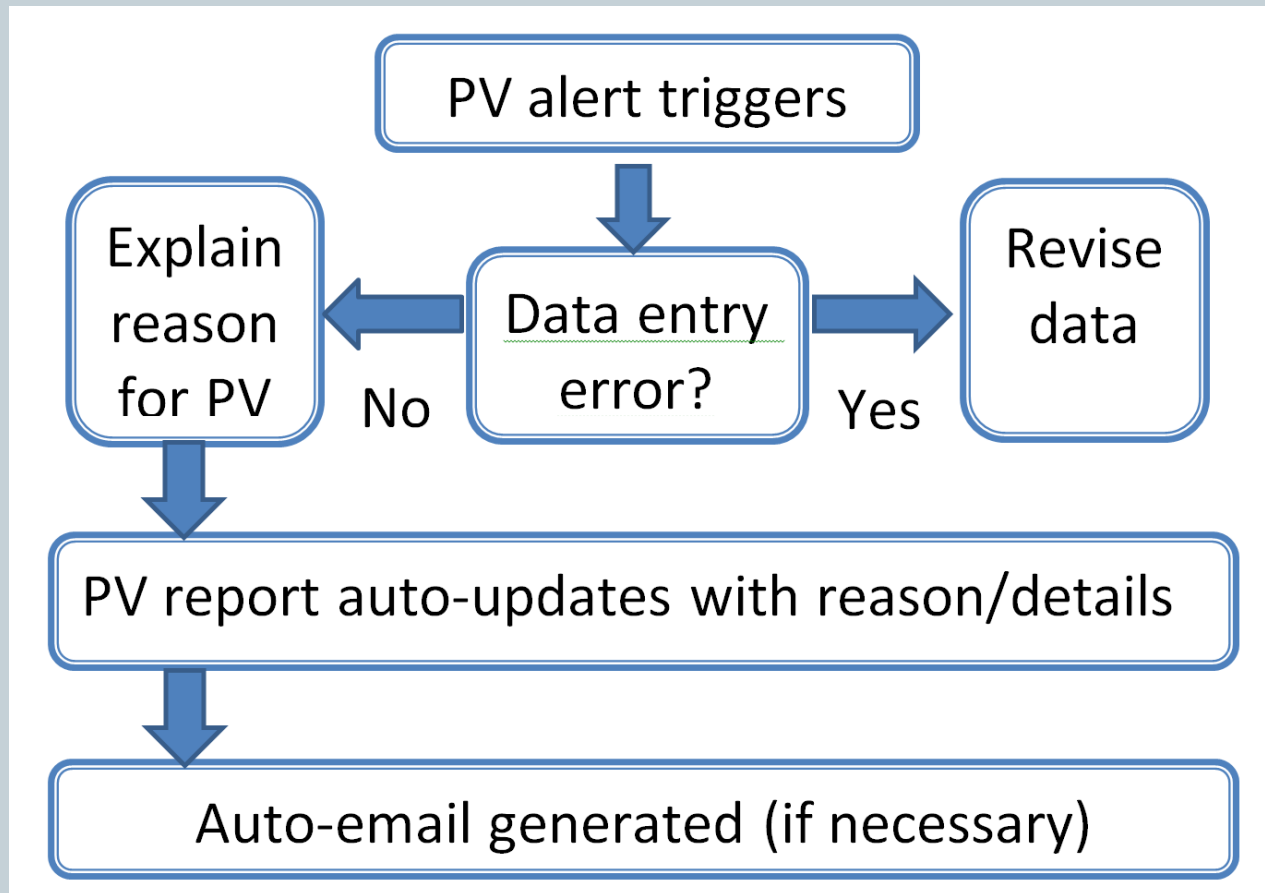
Yes

Unknown

P148

If 'Yes', this is a protocol violation.

# Responding to a PV alert



# Case Study: Reasons for data changes in response to PV alerts in a study database



# Overview



- **Sample size: 1,140 (430 enrolled at the time of this analysis)**
- **Subjects followed for 6 months**
- **Total possible CRFs per subject: 536**
- **Average CRFs completed per subject: 81**
- **Total data validation rules: 784**
- **Total data validation PV rules: 47**

# Number of PV alerts triggered and site response



<b>PV confirmed by site</b>	<b>154</b>
<b>Data changed by site</b>	<b>274</b>
<b>PV confirmed and data changed by site</b>	<b>31</b>
<b>Total</b>	<b>459</b>



# Reasons for data changes in response to PV alerts



<i>Cross-form CRF data entry error</i>	<i>27%</i>
<i>Complex form layout - data entry error</i>	<i>21%</i>
<i>Cross-form regulatory document error</i>	<i>19%</i>
<i>Difficulty understanding question wording</i>	<i>9%</i>
<i>Misuse of calendar tool</i>	<i>5%</i>
<i>Monitor query</i>	<i>3%</i>
<i>Other</i>	<i>16%</i>

# Reducing data changes and data entry errors



- Avoid collecting redundant data on multiple forms.
- Collect times/dates for sequence checking on the same form if possible.
- Keep CRF design and formatting simple. Reduce complex CRFs with multiple columns/rows.
- Keep CRF question wording simple.

# Acknowledgements



- **This work was funded through two NIH/NINDS grants:**
  - Neurological Emergencies Treatment Trial (NETT) Network (U01 NS059041)
  - Progesterone for the Treatment of Traumatic Brain Injury (ProTECT) Trial (U01 NS062778).

**Thank You**

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