PROTECT-CH
Safety Reporting

```
Care home or GP become
aware of a reportable Serious
Adverse Event
        │
        ▼
Serious Adverse Event form
completed by care home or GP
in trial database
        │
        ▼
PI (or delegated trial doctor)
notified by alert stating safety
event occurred
        │
        ▼
◆ Further information needed to
  make relatedness assessment?
   │ No                    │ Yes
   ▼                        ▼
PI (or delegated trial doctor)   Care home or GP contacted for
assesses relatedness             further information
   │
   ▼
◆ Related?
  Yes              No
   │                │
   ▼                ▼
◆ Expected?      Include in
 No     Yes       DMC reports
  │       │
  ▼       ▼
Expedited    Event captured
reporting    within DSUR
```

Treatment adherence and
targeted adverse events
        │
        ▼
Care home enters data into
weekly treatment adherence
and targeted adverse event
checklist

Independent adjudcators carry out consisteny review on reported events and feedback to PI (or delegate) where inconsistencies are identified