# TraCS DSMB Report

# MODERATE & HIGH-RISK Clinical Trials

# REPORT DATE: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_

**Study IRB Number:**

**Study Title:**

Principal Investigator:

Name of Person Submitting Form:

Phone Number and Email Address:

# Review Frequency (check one): Annual Semi-annual Quarterly Interim

# Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Data reported as of \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (date)

1. Are there study-stopping rules for toxicity/safety in this study?  YES NO

2. Are there study-stopping rules for response in this study?  YES NO

3. *If “YES” to question 1 or 2, please include the stopping-rules language or chart.*

4. Are there subject-stopping rules in this study? YES NO

5. *If yes to question 4, please describe subject stopping rules.*

6. Summarize all **grade 3 or greater** adverse events (if any) to date using protocol-defined criteria.

7. Describe any significant safety issues, developments, unexpected toxicities, or concerns that have arisen since the time of last review. Examples: *Describe any toxicities and their relationship to established stopping rules; Attach minutes from team meetings in which toxicities and stopping rules were discussed.*

8. Describe any significant changes to the protocol since the time of last review. *(Attach an up-to-date copy of the IRB application and safety monitoring plan for this protocol)*

SECTION I: Enrollment Data

1. Please describe the anticipated enrollment timeline and enrollment goals for this study

2. Please describe current enrollment situation and if enrollment goals are being met. If accrual or retention rates are insufficient to meet enrollment goals, what actions are in place to increase those rates?

*For table below, descriptive text or additional rows may be added to describe enrollment trends. This may include defining ‘enrolled’ vs ‘randomized’ vs ‘screened’ based on the study.*

**Table 1a: *Recruitment / Enrollment Summary***

|  |  |
| --- | --- |
|  | Study Numbers |
| Total **enrollment** # approved by IRB |  |
| Total # **screened** in the study to date |  |
| Total # **randomized/enrolled** in the study to date |  |
| Total # **screened** in the past year |  |
| Total # **randomized/enrolled** in past year |  |
| Projected # to be randomized/enrolled in coming year |  |
| Total # discontinued |  |
| Start date for enrollment |  |
| Anticipated stop date for enrollment |  |

*If DSMB review is* ***blinded****, enter numbers in the total column only. If DSMB review is* ***unblinded****, enter numbers under each arm as well as total. Additional columns may be added as needed.*

**Table 1b1: *Subject Disposition* (Since the last report)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Subject Disposition** |  |  |  |
| Screened (consented) |  |  | # |
| Randomized | # | # | # |
| Currently in trial | # (%) | # (%) | # (%) |
| Completed trial | # (%) | # (%) | # (%) |
| Discontinued trial | # (%) | # (%) | # (%) |

**Table 1b2: *Subject Disposition* (All subjects to date)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Subject Disposition (all subjects)** |  |  |  |
| Screened (consented) |  |  | # |
| Randomized | # | # | # |
| Currently in trial | # (%) | # (%) | # (%) |
| Completed trial | # (%) | # (%) | # (%) |
| Discontinued trial | # (%) | # (%) | # (%) |

Table 1c1: *Reasons for Discontinuations for any subject discontinued from study (Since the last report)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Primary Reason for**  **Discontinuation** |  |  |  |
| Adverse event(s) | # (%) | # (%) | # (%) |
| Subject lost to follow-up | # (%) | # (%) | # (%) |
| Subject non-compliance | # (%) | # (%) | # (%) |
| Serious adverse event(s) | # (%) | # (%) | # (%) |
| Death | # (%) | # (%) | # (%) |
| Other reason | # (%) | # (%) | # (%) |
|  |  |  |  |

Table 1c2: *Reasons for Discontinuations for any subject discontinued from study* (All subjects to date)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Primary Reason for**  **Discontinuation – All Subjects** |  |  |  |
| Adverse event(s) | # (%) | # (%) | # (%) |
| Subject lost to follow-up | # (%) | # (%) | # (%) |
| Subject non-compliance | # (%) | # (%) | # (%) |
| Serious adverse event(s) | # (%) | # (%) | # (%) |
| Death | # (%) | # (%) | # (%) |
| Other reasons | # (%) | # (%) | # (%) |
|  |  |  |  |

Table 1d: *Primary Reason for Discontinuations, by Subject*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject  Number | Study Arm or Treatment | Randomization  Date | Discontinuation  Date | Last Completed Visit | Primary Reason for Discontinuation | Comments |
| *Example text*  *#005* | *Active Drug* | *2-1-2010* | *3-5-2010* | *3-5-2010* | *Non-compliance* | *Stopped drug X 2 wks* |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
|  |  |  |  |  |  |  |

*Any information added since the last report should be indicated with bolded or colored text.*

SECTION II: Subject Specific Data.

*Indicate subject data by study arm if DSMB review is unblinded*

*For the tables below, please feel free to add descriptive text or additional rows/columns as necessary to aid in the explanation or enable assessment of safety trends.*

Table 2a: *Serious Adverse Events, by Arm and Relationship to Treatment/Study Drug*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Subject  Number | Study Arm or Treatment | Date of SAE | \*Relationship to Treatment/ Study Drug | Study Discontinuation  Y or N | Description of Event |
| *Example text: 006* | *Active* | *4-5-2010* | *Possibly* | *Yes* | *Anaphylactic reaction within ½ hr drug admin.* |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
|  |  |  |  |  |  |

*Any information added since the last report should be indicated with bolded or colored text.*

***\* Relationship:*** *Definitely Related, Probably Related, Possibly Related, Not Related, Unknown*

Table 2b: *Adverse Events, by Severity, Relationship to Study Drug, and Discontinuation*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Number of Adverse Events, by Severity** |  |  |  |
| All severities | # | # | # |
| Mild | # (%) | # (%) | # (%) |
| Moderate | # (%) | # (%) | # (%) |
| Severe | # (%) | # (%) | # (%) |
| Life-threatening | # (%) | # (%) | # (%) |
| **Number of Subjects with at least**  **One Adverse Event, by Severity** |  |  |  |
| All severities | # (%) | # (%) | # (%) |
| Mild | # (%) | # (%) | # (%) |
| Moderate | # (%) | # (%) | # (%) |
| Severe | # (%) | # (%) | # (%) |
| Life-threatening | # (%) | # (%) | # (%) |
| **Number of Adverse Events, by**  **Relationship to Study Drug/Tx** |  |  |  |
| Not Related | # (%) | # (%) | # (%) |
| Probably Related | # (%) | # (%) | # (%) |
| Definitely Related | # (%) | # (%) | # (%) |
| Unknown | # (%) | # (%) | # (%) |
| **Number of Adverse Events Leading**  **To Study Discontinuation** |  |  |  |
| All severities | # (%) | # (%) | # (%) |
| Mild | # (%) | # (%) | # (%) |
| Moderate | # (%) | # (%) | # (%) |
| Severe | # (%) | # (%) | # (%) |
| Life-threatening | # (%) | # (%) | # (%) |
|  |  |  |  |

Table 2c: *Adverse Events Leading to Study Discontinuation*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject  Number | Study Arm or Treatment | Study Visit or Date | \*\*Severity | \*Relationship to Treatment/ Study Drug | Category (AE Term) | Description of Event |
| *Example text:*  *#009* | *Placebo (Arm B)* | *4-15-2010* | *Moderate* | *Unknown* | *GI Symptoms* | *Stomach upset after starting drug* |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
|  |  |  |  |  |  |  |

*Any information added since the last report should be indicated with bolded or colored text.*

***\* Relationship:*** *Definitely Related, Probably Related, Possibly Related, Not Related, Unknown*

***\*\* Severity:*** *Mild, Moderate, Severe or Grades 1 – 5*

Table 2d1: *Adverse Events, by Category and Severity – Moderate Severity or Higher*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Number of Adverse Events by Category,**  **Moderate Severity or Higher** |  |  |  |
| *Example text: Shortness of breath* | *3 (17 %)* | *3 (19%)* | *6 (18 %)* |
| *Hypertension* | # (%) | # (%) | # (%) |
| *GI Symptoms* | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
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|  | # (%) | # (%) | # (%) |
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|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
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|  | # (%) | # (%) | # (%) |
|  |  |  |  |

*Any information added since the last report should be indicated with bolded or colored text.*

Table 2d2: *Adverse Events, by Category and Severity – All Severities*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)  N = # | Placebo (Arm B)  N = # | Total  N = # |
| **Number of Adverse Events by Category,**  **All Severities** |  |  |  |
| *Shortness of breath* | *3 (17 %)* | *3 (19%)* | *6 (18 %)* |
| *Hypertension* | # (%) | # (%) | # (%) |
| *GI Symptoms* | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
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|  | # (%) | # (%) | # (%) |
|  |  |  |  |

*Any information added since the last report should be indicated with bolded or colored text.*

Table 3: *All Randomized Patients (Do not include screen failure subjects or subjects that did not receive the intervention)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject  Number | Study Arm or Treatment | Tx Start Date | Tx End Date | Most Recent Study Visit | Grade 2 -4 or Serious Adverse Events | Study Status |
| *Example text: 001* | *Placebo* | *4-5-2010* | *8-5-2010* | *Month 4* | *None* | *Completed* |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
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| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
|  |  |  |  |  |  |  |

*Any information added since the last report should be indicated with bolded or colored text.*