An SAE is any AE occurring at any dose that:

- Results in death;
- Is life-threatening (i.e., in the opinion of the Investigator, the subject is at immediate risk of death from the AE);
- Requires inpatient hospitalization or prolongation of existing hospitalization (hospitalization is defined as an inpatient admission, regardless of length of stay);
- Results in persistent or significant disability/incapacity (a substantial disruption of the subject’s ability to conduct normal life functions);
- Is a congenital anomaly/birth defect;
- Constitutes an important medical event.

Important medical events are defined as those occurrences that may not be immediately life-threatening or result in death, hospitalization, or disability, but may jeopardize the subject or require medical or surgical intervention to prevent one of the other outcomes listed above. Medical and scientific judgment should be exercised in deciding whether such an AE should be considered serious.

Events not considered to be SAEs are hospitalizations for:

- A standard procedure for protocol therapy administration. However, hospitalization or prolonged hospitalization for a complication of therapy administration will be reported as an SAE.
- Routine treatment or monitoring of the studied indication not associated with any deterioration in condition.
- The administration of blood or platelet transfusion as routine treatment of studied indication. However, hospitalization or prolonged hospitalization for a complication of such transfusion remains a reportable SAE.
- A procedure for protocol/disease-related investigations (e.g., surgery, scans, endoscopy, sampling for laboratory tests, bone marrow sampling). However, hospitalization or prolonged hospitalization for a complication of such procedures remains a reportable SAE.
- Hospitalization or prolongation of hospitalization for technical, practical, or social reasons, in absence of an AE.
- A procedure that is planned (i.e., planned prior to start of treatment on study); must be documented in the source document and the eCRF. Hospitalization or prolonged hospitalization for a complication remains a reportable SAE.
- An elective treatment of or an elective procedure for a pre-existing condition, unrelated to the studied indication that has not worsened from baseline.
- Emergency outpatient treatment or observation that does not result in admission, unless fulfilling other seriousness criteria above.

If an AE is considered serious, both the AE page/screen of the eCRF and the SAE Report Form must be completed.
For each SAE, the Investigator will provide information on severity, start and stop dates, relationship to the IP, action taken regarding the IP, and outcome.

**Severity/Intensity**

For both AEs and SAEs, the Investigator must assess the severity of the event. The severity of AEs will be graded based upon the subject’s symptoms according to the current version of the Common Terminology Criteria for Adverse Events (CTCAE, Version 4.0 or higher).

AEs that are not defined in the CTCAE should be evaluated for severity according to the following scale:

- **Grade 1** = Mild – transient or mild discomfort; no limitation in activity; no medical intervention/therapy required.
- **Grade 2** = Moderate – mild to moderate limitation in activity, some assistance may be needed; no or minimal medical intervention/therapy required.
- **Grade 3** = Severe – marked limitation in activity, some assistance usually required; medical intervention/therapy required, hospitalization is possible.
- **Grade 4** = Life-threatening – extreme limitation in activity, significant assistance required; significant medical intervention/therapy required, hospitalization or hospice care probable.
- **Grade 5** = Death - the event results in death.

Seriousness, not severity, serves as a guide for defining regulatory obligations.

**Causality**

The Investigator must determine the relationship between the administration of the IP and the occurrence of an AE/SAE as Not Suspected or Suspected as defined below:

- **Not suspected:** a causal relationship of the adverse event to IP administration is **unlikely or remote**, or other medications, therapeutic interventions, or underlying conditions provide a sufficient explanation for the observed event.

- **Suspected:** there is a **reasonable possibility** that the administration of IP caused the adverse event. ‘Reasonable possibility’ means there is evidence to suggest a causal relationship between the IP and the adverse event.

Causality should be assessed and provided for every AE/SAE based on currently available information. Causality is to be reassessed and provided as additional information becomes available.

If an event is assessed as suspected of being related to a comparator, ancillary or additional IP that has not been manufactured or provided by Celgene, please provide the name of the manufacturer when reporting the event.
**Duration**

For both AEs and SAEs, the Investigator will provide a record of the start and stop dates of the event.

**Action Taken**

The Investigator will report the action taken with IP as a result of an AE or SAE, as applicable (eg, discontinuation, interruption, or dose reduction of IP, as appropriate) and report if concomitant and/or additional treatments were given for the event.

**Outcome**

The Investigator will report the outcome of the event for both AEs and SAEs. All SAEs that have not resolved upon discontinuation of the subject’s participation in the study must be followed until recovered (returned to baseline), recovered with sequelae, or death (due to the SAE).

**Abnormal Laboratory Values**

An abnormal laboratory value is considered to be an AE if the abnormality:

- results in discontinuation of study treatment;
- requires treatment, modification/ interruption of IP dose, or any other therapeutic intervention; or
- is judged to be of significant clinical importance, eg, one that indicates a new disease process and/or organ toxicity, or is an exacerbation or worsening of an existing condition.

Regardless of severity grade, only laboratory abnormalities that fulfill a seriousness criterion need to be documented as a serious adverse event.

If a laboratory abnormality is one component of a diagnosis or syndrome, then only the diagnosis or syndrome should be recorded on the AE page/screen of the eCRF. If the abnormality was not a part of a diagnosis or syndrome, then the laboratory abnormality should be recorded as the AE. If possible, the laboratory abnormality should be recorded as a medical term and not simply as an abnormal laboratory result (eg, record thrombocytopenia rather than decreased platelets).

**Reporting of Serious Adverse Events**

Any AE that meets any criterion for an SAE requires the completion of an SAE Report Form in addition to being recorded on the AE page/screen of the eCRF. All SAEs must be reported to Celgene Drug Safety within 24 hours of the Investigator’s knowledge of the event by facsimile, or other appropriate method (eg, via email), using the SAE Report Form, or approved equivalent form. This instruction pertains to initial SAE reports as well as any follow-up reports.

The Investigator is required to ensure that the data on these forms is accurate and consistent. This requirement applies to all SAEs (regardless of relationship to study treatment) that occur during the study (from the time the subject signs informed consent until 28 days after the last
SAE håndtering i protokol CC-92480-MM-001

dose of CC-92480 or dexamethasone, or any SAE made known to the Investigator at any time thereafter that are suspected of being related to CC-92480. Serious adverse events occurring prior to treatment (after signing the ICF) will be captured.

The SAE report should provide a detailed description of the SAE and include a concise summary of hospital records and other relevant documents. If a subject died and an autopsy has been performed, copies of the autopsy report and death certificate are to be sent to Celgene Drug Safety as soon as these become available. Any follow-up data should be detailed in a subsequent SAE Report Form, or approved equivalent form, and sent to Celgene Drug Safety.

Where required by local legislation, the Investigator is responsible for informing the Institutional Review Board/Ethics Committee (IRB/EC) of the SAE and providing them with all relevant initial and follow-up information about the event. The Investigator must keep copies of all SAE information on file including correspondence with Celgene and the IRB/EC.

Safety Queries

Queries pertaining to SAEs will be communicated from Celgene Drug Safety to the site via facsimile or electronic mail. The response time is expected to be no more than five (5) business days. Urgent queries (eg, missing causality assessment) may be handled by phone.

Expedited Reporting of Adverse Events

For the purpose of regulatory reporting, Celgene Drug Safety will determine the expectedness of events suspected of being related to CC-92480 based on the IB.

In the United States, all SUSARs will be reported in an expedited manner in accordance with 21 CFR 312.32.

For countries within the EEA, Celgene or its authorized representative will report in an expedited manner to Regulatory Authorities and Ethics Committees concerned, SUSARs in accordance with Directive 2001/20/EC (European Commission) and the Detailed Guidance on collection, verification and presentation of adverse reaction reports arising from clinical trials on investigational products for human use (ENTR/CT3) and also in accordance with country-specific requirements.

For the purpose of regulatory reporting in the EEA, Celgene Drug Safety will determine the expectedness of events suspected of being related to the other investigational product, dexamethasone, based on the EU SmPC.

Celgene or its authorized representative shall notify the Investigator of the following information:

- Any AE suspected of being related to the use of CC-92480 in this study or in other studies that is both serious and unexpected (ie, SUSAR);
- Any finding from tests in laboratory animals that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity, or carcinogenicity.

Where required by local legislation, the Investigator shall notify his/her IRB/EC promptly of these new serious and unexpected AE(s) or significant risks to subjects.
The Investigator must keep copies of all pertinent safety information on file including correspondence with Celgene and the IRB/EC. (See Section 14.3 for record retention information).

**Celgene Drug Safety Contact Information:**

For Celgene Drug Safety contact information, please refer to the Serious Adverse Event Report Form Completion Guidelines or to the Pregnancy Report Form Completion Guidelines.
SAFETY ADVERSE EVENT (SAE) REPORT FORM
Protocol No: CC-92480-MM-001

Subject ID: __ __ __-__ __ __ __

Date: __ __ / __ __ __ / __ __ __ __  
DD     MMM     YYYY

Study Title: A Phase 1 Multicenter, Open-label Study to Assess the Safety, Pharmacokinetics and Preliminary Efficacy of CC-92480 in Combination with Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma

It is recommended that a new form be used for reporting follow-up information; however, the same initial report may be used for minor corrections. If the same form is used, all corrections should be initialed and dated. Please document any changes in the narrative description section of the form.

<table>
<thead>
<tr>
<th>Subject Information:</th>
<th>Country:</th>
</tr>
</thead>
</table>
| Date of Birth: __ __ / __ __ __ / __ __ __ __  
DD     MMM     YYYY |
| Or Age: __ __ years / months(circle one) |
| Sex:  
□ Male  
□ Female |
| Height: □ inches/□ cm: |
| Weight: □ lbs/ □ Kg: |
| Race: Check One:  
□ White  
□ Black  
□ American Indian or Alaska Native  
□ Asian  
□ Pacific Islander |
| Or □ Other, specify: ____________________ |

<table>
<thead>
<tr>
<th>SAE Information (1 event term/diagnosis to this page; if multiple events, complete subsequent forms for SAE #2, SAE #3, etc.)</th>
</tr>
</thead>
</table>
| SAE # 1 Term (as a medical diagnosis):  
(Please check Serious criteria below) |

<table>
<thead>
<tr>
<th>Severity/Intensity: Grade</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional AEs attached</td>
<td>□</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Was the event the result of an overdose of study drug CC92480 and/or dexamethasone?

□ No  
OR □ Yes, CC-92480 Overdose: ______ mg  
Date: _____/_____/_____.  
□ Yes, dexamethasone Overdose: ______ mg  
Date: _____/_____/_____.  
(please provide details in treatment section and narration section, as applicable.)

| Start Date: Date of FIRST sign/symptom of event:  
____ / ____ / __ __ __ __  
DD     MMM     YYYY |
|-------------------------------------------------|------------------|
| Seriousness Criteria: (check ✓) all that apply: | 1. Death  
2. Life threatening  
3. Inpatient hospitalization or prolongation of hospitalization  
4. Persistent/significant disability or incapacity  
5. Congenital anomaly/birth defect  
6. Other important medical event* |

*Should only be used if no other serious criterion applies; or for EOI, if applicable

| Stop Date: Date all signs/symptoms of event resolved:  
____ / ____ / __ __ __ __  
DD     MMM     YYYY |
|-------------------------------------------------|

| Outcome of SAE |  
□ Death (from SAE)  
(Date of death: __ __ / __ __ __ / __ __ __ __) |
|----------------|
| Autopsy done  
□ yes  
□ no Provide death certificate / autopsy results when available |
| □ Not resolved  
□ Resolved  
□ Resolved with sequelae Please provide sequelae |
| □ Unknown: Reason unknown: ____________________ |
SAFETY ADVERSE EVENT (SAE) REPORT FORM

Protocol No: CC-92480-MM-001

Initial or Follow-up Report

Date: ______/____/______

DD MMM YYYY

Subject ID: __ __ __ - __ __ __ __ Site Number - Subject Number

CAUSALITY / RELATIONSHIP to study treatment CC-92480

If "Not Applicable" applies (e.g pre-treatment event), check "Not related"; provide alternative explanation below

The SAE is ☐ Yes (Related) OR ☐ No (not related) *

CAUSALITY / RELATIONSHIP to dexamethasone

If "Not Applicable" applies (e.g pre-treatment event), check "Not related"; provide alternative explanation below

The SAE is ☐ Yes (Related) OR ☐ No (not related) *

*Alternative explanation(s): Check (✓) all that apply. Must be completed if relationship is "Not related" to study drug

☐ Study Indication: ___________________________________________________________

☐ Protocol study related, specify _____________________________________________

☐ Concomitant Illness, specify ______________________________________________

☐ Concomitant Medications, specify __________________________________________

☐ Other Cause, specify _____________________________________________________

TREATMENT / DOSING INFORMATION

☐ Part 1 – Dose Escalation ☐ Part 2 – Cohort Expansion

☐ Cohort 1 ☐ Cohort 2 ☐ Cohort 3 ☐ Cohort 4

☐ Cohort 5 ☐ Cohort 6 ☐ Cohort 7 ☐ Cohort 8

Study Period SAE occurred in:

☐ Pre-Treatment (pre-CC-92480 + dexamethasone)

☐ Treatment Period (CC-92480 + dexamethasone)

☐ Post-end of Treatment (follow up period post last dose of CC-92480 + dexamethasone treatment)

Dosing Information: Complete (CC-92480 + dexamethasone details).

Cycle 1 Day 1

1st dose of study therapy (CC-92480 + dexamethasone):

<table>
<thead>
<tr>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC-92480: ___ ___ mg:</td>
<td>once a day (QD) ☐ twice a day (BID) ☐ Other, specify ______ or</td>
</tr>
<tr>
<td>☐ Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

Start date: __ __ / __ __ __ / __ __ __ __

DD MMM YYYY

Dexamethasone: ☐ 20 mg ☐ 40 mg ☐ Other, specify ______

☐ Once a day (QD), ☐ Other, specify ______ or ☐ Not applicable

Start date: __ __ / __ __ __ / __ __ __ __

DD MMM YYYY

Last dose of study therapy prior to event:

Cycle _____ Day _____ (CC-92480 + dexamethasone):

<table>
<thead>
<tr>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC-92480: ___ ___ mg:</td>
<td>once a day (QD) ☐ twice a day (BID) ☐ Other, specify ______</td>
</tr>
<tr>
<td>☐ Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

End date: __ __ / __ __ __ / __ __ __ __

DD MMM YYYY

Dexamethasone: ☐ 20 mg ☐ 40 mg ☐ Other, specify ______

☐ Once a day (QD), ☐ Other, specify ______ or ☐ Not applicable

End date: __ __ / __ __ __ / __ __ __ __

DD MMM YYYY

Please include explanation for any dosing modification(s) in the narrative page.
SAFETY ADVERSE EVENT (SAE) REPORT FORM

Protocol No: CC-92480-MM-001  □ Initial  or □ Follow-up Report

Date: __ __ __/ __ __ __/ __ __ __

Subject ID: __ __ __- __ __ __ __ Site Number - Subject Number

### Action taken with study medication (due to this event)*:

Record only 1 action taken for each AE. Choose the "worst-case" scenario: Discontinued > Dose interrupted > New Dose > None. The dates should be captured in dd/mmm/yyyy. Indicate the action taken for study drug as a result of this AE with an "X" in the appropriate box and dates/information, as indicated.

<table>
<thead>
<tr>
<th>Action taken with CC-92480</th>
<th>None</th>
<th>Interrupt: Stop date: __ __ / __ __ __/ __ __ __ __ Restart date: __ __ / __ __ __ / __ __ __ __</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>New dose ________mg: Start date: __ __ / __ __ __ / __ __ __ __</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinuation: Stop date: __ __ / __ __ __ / __ __ __ __</td>
</tr>
</tbody>
</table>

Dechallenge/ Rechallenge Did SAE abate after dose interruption or stopping? □ Yes* □ No □ Not applicable

*If yes, did SAE reappear after reintroduction? □ Yes □ No □ Not applicable

<table>
<thead>
<tr>
<th>Action taken with dexamethasone</th>
<th>None</th>
<th>Interrupt: Stop date: __ __ / __ __ __ / __ __ __ __ Restart date: __ __ / __ __ __ / __ __ __ __</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>New dose ________mg: Start date: __ __ / __ __ __ / __ __ __ __</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinuation: Stop date: __ __ / __ __ __ / __ __ __ __</td>
</tr>
</tbody>
</table>

Dechallenge/ Rechallenge Did SAE abate after dose interruption or stopping? □ Yes* □ No □ Not applicable

*If yes, did SAE reappear after reintroduction? □ Yes □ No □ Not applicable
SAFETY ADVERSE EVENT (SAE) REPORT FORM
Protocol No: CC-92480-MM-001 □ Initial or □ Follow-up Report
Date: __ __ / __ __ / ______

Subject ID: ______ - ______
Site Number - Subject Number

SAE Information
SAE #__ Term (as a medical diagnosis): ________________________________
(Please check Serious criteria below)

Severity/Intensity: Grade [□ 1 □ 2 □ 3 □ 4 □ 5]
□ Additional AEs attached
If reporting multiple AEs, attach an Additional AE page for each additional AE you are reporting.

Date of FIRST sign/symptom of event: __ __ / __ __ __ / __ __ __ __
DD MMM YYYY
Date all signs/symptoms of event resolved: __ __ / __ __ __ / __ __ __ __
DD MMM YYYY
Or □ Ongoing

Seriousness Criteria: (check ✓ all that apply):
□ 1. Death
□ 2. Life threatening
□ 3. Inpatient hospitalization or prolongation of hospitalization
□ 4. Persistent/significant disability or incapacity
□ 5. Congenital anomaly/birth defect
□ 6. Other important medical event*
*Should only be used if no other serious criterion applies or for EOI, if applicable

Outcome of SAE
□ Death (from SAE) (Date of death: __ __ / __ __ __ / __ __ __ __)
Autopsy done □ yes □ no Provide death certificate / autopsy results when available
□ Not resolved
□ Resolved
□ Resolved with sequelae. Please provide sequelae __________________________
□ Unknown: Reason unknown: _____________________________________________

CAUSALITY / RELATIONSHIP to study treatment CC-92480
If ‘Not Applicable’ applies (eg, pre-treatment event), check ‘Not related; provide alternative explanation below
The SAE is □ Yes (Related) OR □ No (not related) *

CAUSALITY / RELATIONSHIP to Dexamethasone
If ‘Not Applicable’ applies (eg, pre-treatment event), check ‘Not related; provide alternative explanation below
The SAE is □ Yes (Related) OR □ No (not related) *

*Alternative explanation(s): Check ✓ all that apply. Must be completed if relationship is “Not related” to study drug
□ Study Indication
□ Protocol Related, specify _____________________________________________
□ Concurrent illness, specify _____________________________________________
□ Concomitant Medications, specify _________________________________________
□ Other Cause, specify ___________________________________________________
SAFETY ADVERSE EVENT (SAE) REPORT FORM

Protocol No: CC-92480-MM-001 □ Initial or □ Follow-up Report
Date: ______ / ______ / ______ DD  MMM  YYYY

Subject ID: __________________________ Site Number - Subject Number

### Action taken with study medication (due to this event)*:

Record only 1 action taken for each AE. Choose the "worst-case" scenario: Discontinued > Dose interrupted > New Dose > None. The dates should be captured in dd/mmm/yyyy.

Indicate the action taken for study drug as a result of this AE with an "X" in the appropriate box and dates/information, as indicated.

<table>
<thead>
<tr>
<th>Action taken with CC-92480</th>
<th>None</th>
<th>Interrupt: Stop date: __ __ / __ __ __ / __ __ __ __</th>
<th>Restart date: __ __ / __ __ __ / __ __ __ __</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DD  MMM  YYYY</td>
<td>DD  MMM  YYYY</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>New dose ________mg: Start date: __ __ / __ __ __ /</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>DD  MMM  YYYY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinuation: Stop date: __ __ / __ __ __ /</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>DD  MMM  YYYY</td>
<td></td>
</tr>
<tr>
<td>Dechalleng/</td>
<td>Did SAE abate after dose interruption or stopping?</td>
<td>□ Yes* □ No □ Not applicable</td>
<td></td>
</tr>
<tr>
<td>Rechallenge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*If yes, did SAE reappear after reintroduction?</td>
<td>□ Yes □ No □ Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

| Action taken with          | None | Interrupt: Stop date: __ __ / __ __ __ / __ __ __ __ | Restart date: __ __ / __ __ __ / __ __ __ __ |
| dexamethasone             |      | DD  MMM  YYYY                                       | DD  MMM  YYYY                                    |
|                           |      |                                                     |                                                  |
|                           |      | New dose ________mg: Start date: __ __ / __ __ __ / |                                                  |
|                           |      | DD  MMM  YYYY                                       |                                                  |
|                           |      |                                                     |                                                  |
|                           |      | Discontinuation: Stop date: __ __ / __ __ __ /       |                                                  |
|                           |      | DD  MMM  YYYY                                       |                                                  |
| Dechalleng/              | Did SAE abate after dose interruption or stopping?  | □ Yes* □ No □ Not applicable                      |
| Rechallenge             |                                             |                                                 |
|                          | *If yes, did SAE reappear after reintroduction?     | □ Yes □ No □ Not applicable                      |
SAFETY ADVERSE EVENT (SAE) REPORT FORM
Protocol No: CC-92480-MM-001 □ Initial or □ Follow-up Report
Date: ___ / ___ / ______

Subject ID: ______ - ________
Site Number - Subject Number

<table>
<thead>
<tr>
<th>OTHER MEDICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used within 28 days prior to start of AE(s); Attach additional medication sheets if necessary</td>
</tr>
<tr>
<td>Data from eCRF may be attached, if data entry is current □ List attached</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication and dosing regimen (dose with units/frequency/route)</th>
<th>Start Date (DD/MMM/YYYY)</th>
<th>Stop Date (DD/MMM/YYYY)</th>
<th>Ongoing? (✓)</th>
<th>Concomitant Medication or Treatment of SAE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 / 1</td>
<td>1 / 1</td>
<td></td>
<td>Treatment medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Concomitant medication*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* indication: ___________________________</td>
</tr>
<tr>
<td></td>
<td>1 / 1</td>
<td>1 / 1</td>
<td></td>
<td>Treatment medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Concomitant medication*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* indication: ___________________________</td>
</tr>
<tr>
<td></td>
<td>1 / 1</td>
<td>1 / 1</td>
<td></td>
<td>Treatment medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Concomitant medication*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* indication: ___________________________</td>
</tr>
<tr>
<td></td>
<td>1 / 1</td>
<td>1 / 1</td>
<td></td>
<td>Treatment medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Concomitant medication*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* indication: ___________________________</td>
</tr>
</tbody>
</table>

Relevant medical and surgical history pertaining to Event

Data from eCRF may be attached, if data entry is current □ List attached

<table>
<thead>
<tr>
<th>Relevant Laboratory and Diagnostic Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please provide substantiating diagnostics RELEVANT to the event being reported. Include dates, units, and normal ranges or □ eCRF copy attached</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Test</th>
<th>Result with Units Included</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY ADVERSE EVENT (SAE) REPORT FORM

Protocol No: CC-92480-MM-001
☐ Initial or ☐ Follow-up Report
Date: _____/_____/______

Subject ID: __ __ __-__ __ __ __
Site Number - Subject Number

AE Narrative Description
With the exception of a death certificate and/or an autopsy report, medical records (e.g. hospital discharge report or hospital records), should NOT be provided unless specifically requested by the sponsor.

Summarize applicable medical records/source documents chronologically for the AE term(s) reported.
Attach additional pages as necessary

Investigator Name (printed):
Investigator Signature/Date:

Reporter Name (printed):
Reporter Signature/Date:

Contact Information: Phone, Fax # and email address:

Hospital name and city: (Spain only):