

Serious Adverse Event Report Form

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718835#0#0

| | | | | | |
|--------------|-------------|-------------------------|----------------------|-----------|--|
| PROTOCOL NO. | JWP-PVA-301 | Investigational Product | JW0101, C2101, C2102 | SITE CODE | |
|--------------|-------------|-------------------------|----------------------|-----------|--|

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|------------------------|--|---------------------------------|--|-------------|--|
| Principal Investigator | | DATE RECOGNIZED BY INVESTIGATOR | | REPORT TYPE | <div><div></div><div></div><div></div><div>(No. <input type="text"/>)</div></div> <div>Initial Follow up</div> |
|------------------------|--|---------------------------------|--|-------------|--|

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I. PATIENT INFORMATION

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| | | | | | | | |
|---------|--|---------------|--|------------|--|-----|--|
| Initial | | Screening No. | | Random No. | | Sex | <div><div></div><div></div><div></div><div>M</div><div>F</div></div> |
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|---------------|-------------------------|-----|--|--------|---------------|---------------|---|
| Date of Birth | <div>(YYYY/MM/DD)</div> | Age | | Weight | <div>kg</div> | Out/Inpatient | <div><div></div><div></div><div></div><div></div><div>Outpatient</div><div>Inpatient</div><div>Others</div></div> <div></div> |
|---------------|-------------------------|-----|--|--------|---------------|---------------|---|

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II. EVENT INFORMATION

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| Serious Adverse Event(s)description | |
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| | | | | | |
|---------------------------|--|----------------------------|--|-------------------------------|--|
| AE Onset Date(YYYY/MM/DD) | | SAE Onset Date(YYYY/MM/DD) | | SAE Resolved Date(YYYY/MM/DD) | |
|---------------------------|--|----------------------------|--|-------------------------------|--|

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In Case of Death,

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| | | | | | | | | |
|----|--|----------------------------|--|--------------------------------------|--|----------|--|-------------|
| NA | <div> <div>[?NULL?]</div> <div></div> </div> | Date of Death(YYYY/MM/DD): | | Reported Cause of Death(YYYY/MM/DD): | | Autopsy: | <div> <div></div> <div></div> <div></div> <div></div> </div> | Y N L |
|----|--|----------------------------|--|--------------------------------------|--|----------|--|-------------|

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| Was death secondary to the SAE? | <div></div> |
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Outcome & Relationship

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| Outcome | <input type="text"/> <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Unknown with sequela <input type="radio"/> Recovering/Other <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Death <input type="radio"/> Unknown | <input type="text"/> <input type="radio"/> Related <input type="radio"/> Unrelated |
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Study Drug Status

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| | | | |
|---|----------------------|--------------------------|---|
| Study drug start date(YYYY/MM/DD): | <input type="text"/> | Study Drug Status | <input type="text"/> <input type="radio"/> Not Applicable <input type="radio"/> Unknown <input type="radio"/> Dose Not Changed <input type="radio"/> Drug Interrupted <input type="radio"/> Drug Withdrawn |
|---|----------------------|--------------------------|---|

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Rechallenge of study drug

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| | | |
|---|-----------------------------|--|
| <p>Rechallenge of study drug</p> <div> <input type="radio"/> Yes <input type="radio"/> No </div> | <p>Date Resumed:</p> | <div> <input type="text"/> (YYYY/MM/DD) </div> |
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III. PREVIOUS / CURRENT DISEASE

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| | |
|----|--|
| NA | <input type="text" value="[NULL]"/> <input type="text"/> NA |
|----|--|

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Please record medical history or still active disease.

| No. | Diagnosis / Allergies / Operation/Others | Onset Date(YYYY/MM/DD) | Resolved Date(YYYY/MM/DD) | Check if continuing | Comment |
|-----|--|------------------------|---------------------------|---------------------|---------|
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추가

718849#0#1

| | | | | | |
|--------|----------------------|----------------------|----------------------|--|----------------------|
| 1 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text" value="[NULL]"/> <input type="text"/> Check if continuing | <input type="text"/> |
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Audit Trail

| | | | | | |
|------------------|----------------------|----------------------|----------------------|--|----------------------|
| #_no_# #_no_# | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text" value="[NULL]"/> <input type="text"/> Check if continuing | <input type="text"/> |
|------------------|----------------------|----------------------|----------------------|--|----------------------|

삭제 지우개 의견 작성 더보기

Audit Trail

IV. CONCOMITANT MEDICATIONS

더보기

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| | |
|----|--|
| NA | <input type="text" value="[NULL]"/> <input type="text"/> NA |
|----|--|

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Audit Trail

Please record all prescription drugs being taken with investigational product.

| No. | Concomitant Drug | Dose | Frequency | Route | Start Date(YYYY/MM/DD) | Stop Date(YYYY/MM/DD) | Reason | Treatment for Event |
|-----|------------------|------|-----------|-------|------------------------|-----------------------|--------|---------------------|
|-----|------------------|------|-----------|-------|------------------------|-----------------------|--------|---------------------|

추가

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| 1 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
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Audit Trail

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| #_no_# #_no_# | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|

삭제 지우개 의견 작성 더보기

Audit Trail

V. LABORATORY TESTS / IMAGING

더보기

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| | |
|----|--|
| NA | <input type="text" value="[NULL]"/> <input type="text"/> NA |
|----|--|

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Please record all laboratory results and imaging tests showing clinically significant change from baseline value.

If needed, attach all other relevant laboratory results and imaging tests.

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| Labs/imaging tests attached | <input type="text" value="[NULL]"/> <input type="text"/> Labs/imaging tests attached |
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Audit Trail

| No. | Test Name | Baseline | | After Adverse Event | | Reference Range(if applicable) | Pending? |
|-----|-----------|------------------|-----------------------|---------------------|-----------------------|--------------------------------|----------|
| | | Date(YYYY-MM-DD) | Result(include units) | Date(YYYY-MM-DD) | Result(include units) | | |

추가

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| <div>1</div> <div>1</div> | | | | | | |
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| | | | | | | |
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| <div>#_no_#</div> <div>#_no_#</div> | | | | | | |
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|---|
|  추가 |
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VI.Investigator's Narration

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| <div>718857#0#0</div> | |
| Please describe all relevant information about the Adverse Event in detail. Please indicate if there have been any significant changes since the previous report. | |

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| <div>718858#0#0</div> | |
| Reporter's Comments | |

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Principal Investigator Signature

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| <div>718859#0#0</div> | | | | | |
| Name | | Date (YYYY-MM-DD) | | Signature | |

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| <div>Y</div> |
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