


For LYSARC only



SAE n°

**SERIOUS ADVERSE EVENT
(SAE)**

MCL R2 ELDERLY

Patient:
1 of last name 1 of first name

Inclusion number:
 8 0 1 2 1

If multiple Serious Adverse Events (if applicable and associated with SAE page 1)

Serious Adverse Event	Seriousness criteria 1. Death from SAE 2. Life-threatening 3. Hospitalization 4. Disability/Incapacity 5. Congenital anomaly 6. Important medical event	Onset date / Date of resolution (dd/mon/yyyy)	CTCAE v4.0 Grade (1 to 5)	Outcome of SAE 1. Recovered 2. Recovered with sequelae 3. Not recovered 4. Death from SAE 5. Ongoing at death	Relationship with 1. Lenalidomide 2. Rituximab SC
2	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes No 1. <input type="checkbox"/> <input type="checkbox"/> 2. <input type="checkbox"/> <input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes No 1. <input type="checkbox"/> <input type="checkbox"/> 2. <input type="checkbox"/> <input type="checkbox"/>

Relevant medical and surgical history:

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Chronologic summary, short description of the SAE (including hospitalization dates):

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Relevant laboratory and diagnostic tests results:

.....

Procedures or Treatment (Active substance) **used to treat SAE:**

.....

Please add to the SAE all pertinent reports: hospitalization summaries, lab analysis, imaging reports...

Reported by:

Name/Function:

Signature:

Medical review by:

Name:

Signature:

Sponsor's assessment: Related

Unrelated

Validated by:

Expectedness: Expected

Unexpected

Date:

Signature: