

## GUIDELINE FOR GCP / PROTOCOL DEVIATIONS

<b>Sponsor:</b>	
<b>Trial Title:</b>	
<b>Trial Code</b>	

Critical deviations are those likely to affect:

- the patient's safety or physical integrity or rights
- the scientific value of the trial

Category	Issue
Patient data protection	Patient identity was inappropriately revealed
Informed consent	Patient did not sign the informed consent
	Investigator did not sign the informed consent
	Patient started the study before Informed consent signature
	Patient did not sign new informed consent version (re-consent)
	<i>&lt;add other issues as appropriate&gt;</i>
Eligibility criteria	Patient did not fulfill all inclusion/exclusion criteria
	<i>&lt;add other issues as appropriate&gt;</i>
Discontinuation criteria	Patient met efficacy withdrawal criteria but was not discontinued
	Patient met safety withdrawal criteria but was not discontinued
	Patient was discontinued by the investigator without meeting discontinuation criteria
	<i>&lt;add other issues as appropriate&gt;</i>
Investigational product	Patient received wrong investigational treatment (wrong treatment arm)

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	Patient received a wrong treatment dose / Dose modification not according to protocol
	Patient/investigator not compliant with treatment dosing schedule
	Patient received expired IMP
	Patient interrupted treatment due to lack of timely IMP supply
	Inappropriate IMP storage temperature
	Inappropriate monitoring of IMP storage conditions
	Inappropriate IMP preparation
	Inappropriate code breaking by investigator
	Inability to timely unblind the treatment code in emergency situation
	<i>&lt;add other issues as appropriate&gt;</i>
Biological samples handling	Inappropriate samples storage temperature
	Inappropriate monitoring of samples storage conditions
	Incorrect samples processing / handling
	<i>&lt;add other issues as appropriate&gt;</i>
Concomitant treatments	Patient took/received prohibited concomitant treatment
	Patient did not take/receive a mandatory concomitant/rescue treatment
	<i>&lt;add other issues as appropriate&gt;</i>
Efficacy assessment	Critical efficacy evaluations for trial endpoints assessment not performed as per protocol (including pre-treatment)
	<i>&lt;add other issues as appropriate&gt;</i>
Safety assessment	Critical safety evaluations for trial endpoints assessment not performed as per protocol (including pre-treatment)
	Critical evaluations to protect patient's safety not performed as required

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	SAE not reported
	SAE not reported according required timelines
	<i>&lt;add other issues as appropriate&gt;</i>
Fraude / misconduct	Patient does not exist
	Investigator created fake documents (e.g., patient signature on informed consent)
	Source documents altered / destroyed to hide non-compliance
	<i>&lt;add other issues as appropriate&gt;</i>
<i>&lt;add other categories as appropriate&gt;</i>	