	Safety Reporting Form - English	
	Version 1.0	Effective 16-May-2022

To be used for primary reporting and as a back-up to Axelys Safety Reporting Portal (ASRP)	
PROJECT TITLE: Pump Up Infusion	
Section 1 – Adverse Event Report / Other Safety Findings / Product Complaint Submission – General	
Send this report to Axelys santé DZ - Preferred Via Email: **pharmacovigilance-dz@axelys-sante.com** - Via phone: 0671 432 009 / 0671 432 202	
Please read/provide to the reporter – '*Axelys santé DZ may process your personal information in order to manage your request, to fulfil Axelys santé DZ's safety obligations, or as required by applicable law*'. If the reporter wishes to hear more about Axelys santé DZ's privacy practices, please click *here and provide	
*= Mandatory Fields	
Organization Code* *(e.g., PSP-99999, PMR-99999, SMP-99999)*: PSP 10795 Project ID (for MR projects only):	Vendor Reference ID/Respondent ID*: *(Insert Vendor identifier unique for this report to allow cross-reference)*
Follow Up: ☐	Prior Master Case ID Number:
Submitter Name* *(Enter first and last names)*:	Submitter Phone Number*:
Submitter E-mail*:	Country*: Algeria
Date of Awareness (Initial Receipt Date)*:	Date Submitted to Axelys santé DZ*:
Reported by HCP*? If No, please clarify *(e.g., patient, caregiver, relative)*:	☐ *Yes* ☐ No
Consent to Contact HCP*? *(If consent to contact HCP is 'yes', please provide HCP contact details (e.g. Name, Phone, number, or email. At least one contact method must be supplied)*	☐ Yes ☐ No
Consent to Contact Patient*? *(If consent to contact Patient is 'yes', please provide Patient contact details (e.g. Name, Phone, number, or email. At least one contact method must be supplied)*	☐ Yes ☐ No
Consent to Contact Complainant/Reporter*?	☐ Yes ☐ No
Product Name*:	Delivery Method/Dosage Form* *(e.g., tablet, vial, pre-filled syringe)*: *(Insert "unknown"/ "not provided" if not known)*
Lot/Batch Number*: *(Insert "unknown"/ "not provided" if number not known)*	Device Serial Number: *(Insert "unknown"/ "not provided" if number not known)*
Reason for Missing Lot No*: *(If the Lot/Batch Number is marked "unknown"/"not provided", select the appropriate reason for missing lot number. If the Lot/Batch Number is provided, no action is required.)* *Declined to provide lot number* ☐ *Cannot read/cannot find lot number* ☐ *Does not and will never have access to lot number* ☐ *May have access to lot number – please follow up with reporter* ☐	

Other – please explain in the Description ☐ *(enter "other" reason here)*	
Indication/Diagnosis/ICD*: *(Insert "unknown"/"not provided" if not known)*	Dose/Frequency*: *(Insert "unknown"/ "not provided" if not known)*

Section 2 – Patient Details	
First Name or Initial*: *(Initial will suffice if local data privacy prevents insertion of full details or patient prefers to remain anonymous)* *(Insert "unknown"/"not provided" if information not known)*	
Last Name or Initial*: *(Initial will suffice if local data privacy prevents insertion of full details or patient prefers to remain anonymous)* *(Insert "unknown"/"not provided" if detail not known)*	
Patient Primary Phone Number:	Patient E-mail:
Patient Address:	
Patient City:	Patient State/Province:
Patient Country*:	Patient Postal Code:
Patient Age* *(At the time of event)*: *(Insert "unknown"/"not provided" if detail not available)*	Patient Age Unit* *(e.g., months, years)*:
Patient Date of Birth* *(e.g., DD-MMM-YYYY)*: *(Insert "unknown"/"not provided" if detail not available)*	Age Group: *Adolescent* ☐ *Fetal* ☐ *Adult* ☐ *Infant* ☐ *Child* ☐ *Neonate* ☐ *Elderly* ☐
Patient Gender*: *(e.g., male, female, not specified)*	*(Insert "unknown"/"not provided" if detail not available)*

Section 3 – HCP Details	
HCP First Name:	HCP Last Name:
HCP Type *(e.g., Doctor, Pharmacist, Nurse, Other)*	HCP Email Address:

HCP Phone Number:	HCP Fax Number:
HCP Address	HCP City
HCP State/Province:	HCP Country:
HCP Postal Code:	Associated Institution Name:

Section 4 – Adverse Event Report/Other Safety Finding

Description of Adverse Event/Other Safety Finding *:

Section 5 – Product Complaint

Description of Product Complaint*:

Product Available for Return: No ☐ Yes ☐	Replacement Request: *(If yes, DOB must be provided)* No ☐ Yes ☐