



LABEL SPECIFICATION COVER SHEET

Label ID #: ASZ6116
Current Job #: 1203-002-18 RL #2
Original Job #: 1203-002-18 RL #2

Client Part #: N/A
Protocol: RAMPART (FCS#211915) (419705)
Blinded Study: **No**
Label Package Integration: **No**

Client Name: AstraZeneca
Created By: Schubert, Aline 27/Feb/18 8:15:22 AM CET
Updated By: Lidy, Romaric 01/Mar/18 10:26:21 AM CET
Project Manager Sign/Date: Schubert, Aline

Study Logistics	Manufacturing Logistics
Description: Single Panel Vial Label	Design Program: CLPS
Drug Name/Strength: MEDI4736 injection 500 mg NSC 778709 50 mg/mL, 10 mL solution for infusion	TCN#: TCN03422
Container Type: Vial Label	Template ID #: 1.1000.2625.1000.2750.SC1
Languages: 1	Label Type: Single
Blinded Label: No	Open Direction: N/A
Last Coding Job: N/A	Overall Size: 1" x 2 5/8"
Variable Field Associations: F2, F3, F4	Repeat: 2 3/4"
Manufacture Quantity: 1	Gen Strip: N/A
Clintrak PFI Quantity: 0	Backtape: N/A
Special Instructions N/A	Base Label Stock: STK1998 - Semi-Gloss Elite Fascover ES / Opaque / S246 / 50# SCK / Clintrak Part # RLP00013
Change Notices N/A	Booklet Stock: N/A
Deviation Reports N/A	Laminate: N/A
	OSW Stock: N/A
	Mfg Type: Manufacture New
	Blank Stock: No
	New Dies Req'd: Flexo: No
	Base Panel Inks/Varnishes
	Print Station 1: N/A
	Print Station 2: N/A
	Print Station 3: N/A
	Print Station 4: N/A
	Print Station 5: N/A
	Finishing Operations
	Process Type: In-Process
	Blinding Laminate: N/A
	Apply Laminates To: N/A
	Reorient: No
	Press Roll: Yes Core: 6" Max. Diam: 12.75" Unwind: 4

Colors**Content Color 1:** Black**Content Color 2:** N/A**Content Color 3:** N/A**Label Color:** White**Special Instructions:** N/A

Variable Field Requirements			
F #	Placeholder	Placeholder Description	Placements
F1	N/A	N/A	F1: PN1 (6pt)
F2	BBBBBBBBBB	Batch No.	F2: PN1 (6pt)
F3	MM/YYYY	Expiry Date	F3: PN1 (6pt)
F4	XXXXXXXXXX	(Barcode\DataMatrix)	F4: PN1 (16pt)

CUSTOMER AUTHORIZATION

- Proof Approved** Proceed with Order
- Revise Proof** Return for Review

AUTHORIZED SIGNATURE

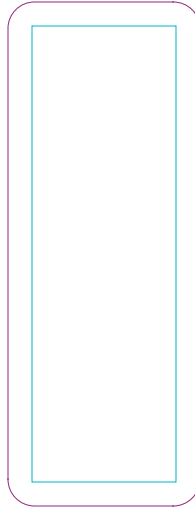
DATE

Customer approval applies to all sections of this label specification cover sheet.



clinical labeling services

CLPS LABEL PROOF



F2

Protocol : RAMPART (RE06) Eudract No: 2017-002329-39

Batch Number : BBBB BBBB Expiry date: MM/YYYY

Patient Trial Number : _____

Site : _____ Principal Investigator : _____

Vial containing MED14736 500mg For intravenous infusion only

Directions for Use: To be administered in accordance with

protocol instructions For Clinical Trial Use only Store between


2-8°C Protect from light Keep out of reach and sight of children

Sponsor : University College London, Gower Street, London, WC1E 6BT ASZ6116

Tel: 020 7679 2000 Chief Investigator: Dr James Larkin

F3

F4



Label ID#: ASZ6116

Label Designed By: Romaric Lidy

Label Revised By: Romaric Lidy

Template ID#: 1.1000.2625.1000.2750.SC1

Client Approval: _____

IPI: **SIGNATURE ON FILE** _____