



LABEL SPECIFICATION COVER SHEET

Label ID #: ASZ6076.1
Current Job #: 1203-002-18 RL #1
Original Job #: 1203-002-18 RL #1

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

Client Name: AstraZeneca
Created By: Schubert, Aline 1/16/2018 11:41:27 AM CET
Updated By: Meier, Lars 2/1/2018 3:12:10 PM CET
Project Manager Sign/Date: Schubert, Aline

Study Logistics		Manufacturing Logistics	
Description:	Single Panel Carton Label - MEDI4736	Design Program:	CLPS
Drug Name/Strength:	MEDI4736 (500mg/vial)	TCN#:	TCN05478
Container Type:	Carton Label	Template ID #:	1.5000.2500.5000.3000.SC1
Languages:	1	Label Type:	Single
Blinded Label:	No	Open Direction:	N/A
Last Coding Job:	N/A	Overall Size:	5" x 2 1/2"
Variable Field Associations:	F2, F3, F4	Repeat:	3"
Manufacture Quantity:	1	Gen Strip:	Clintrak Std.
Clintrak PFI Quantity:	0	Backtape:	N/A
Special Instructions	N/A	Base Label Stock:	LAM2561 - Semi-Gloss Elite / Non-Opaque / S246 / 50# SCK / Clintrak Part # RLP00009
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: 4" Max. Diam: 11" Unwind: 4

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

Variable Field Requirements			
F #	Placeholder	Placeholder Description	Placements
F1	N/A	N/A	F1: PN1 (11pt)
F2	PPPPPPPPPP	Batch No	F2: PN1 (10pt)
F3	MM.YYYY	Expiry Date	F3: PN1 (10pt)
F4	XXXXXXXXXX- XXXXXXXXXX	(Barcode\DataMatrix)	F4: PN1 (20pt)

CUSTOMER AUTHORIZATION

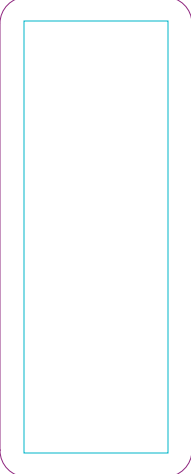
- Proof Approved** Proceed with Order
- Revise Proof** Return for Review

AUTHORIZED SIGNATURE


DATE

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

CLPS LABEL PROOF

F2 

F3 **F4**

Protocol : RAMPART (RE06)	EudraCT No: 2017-002329-39	
Batch Number : P P P P P P P P P P	Expiry date: MM.YYYY	
Site: _____		
Principal Investigator: _____		
Carton containing 3 vials of MEDI4736 500mg		
For intravenous infusion only		
Directions for Use: To be administered in accordance with protocol instructions		
Store between 2-8°C		
Keep out of reach and sight of children		
For Clinical Trial Use only		
Sponsor: University College London, Gower Street, London, WC1E 6BT,		
Tel: 020 7679 2000		
Chief Investigator: Dr James Larkin		

ASZ6076

Label ID#: ASZ6076.1

Label Designed By: Romaric Lidy

Label Revised By: Valerie Zimmermann

Template ID#: 1.5000.2500.5000.3000.SC1

Client Approval: _____

IPI: _____ **SIGNATURE ON FILE**