

Navigating Global Regulations to Deploy the Assay for Global Trials



US (FDA)

Risk Determinations

- IRB
- FDA

IDE Submissions

Q-Submissions

510(k), PMA, De Novo classifications

CellCarta has created **22 Study Risk Determinations** since 2023

- 20 in oncology trials determined to be Non-Significant Risk
- 2 in immunology trials determined to be Significant Risk (1 IDE approved and 1 in progress)



EU (IVDR)

Ethics Committee Submission

IVDR: Annex XIII, XIV

IVDR: CE-Mark (BSI Notified Body)

UK

MHRA
Registrations

CellCarta has created **32 Clinical Performance Study packages** following Annex XIV of IVDR

43 Individual IVDR approvals across 17 countries

Countries in progress: Romania, Bulgaria, Ukraine



CHINA

EC Submissions

HGRAC Submissions

NMPA Inspection

2024 – 20 HGRAC & 5 EC submissions

US	EU	UK	CHINA
Risk Determinations • IRB • FDA	Ethics Committee Submissions	MHRA Registrations	EC Submissions HGRAC Submissions NMPA Inspection
IDE Submissions	IVDR: Annex XIII, XIV		
Q-Submissions	IVDR: CE-Mark (BSI Notified Body)		
510(k), PMA, De Novo classifications			



CellCarta has created **21 Study Risk Determinations** in the last 2 years

- 20 in oncology trials determined to be Non-Significant Risk
- 2 in immunology trials determined to be Significant Risk (1 IDE approved and 1 in progress)

CellCarta has created 25 Clinical Performance Study packages following Annex XIV of IVDR

**43 IVDR
approvals in
17 countries**

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