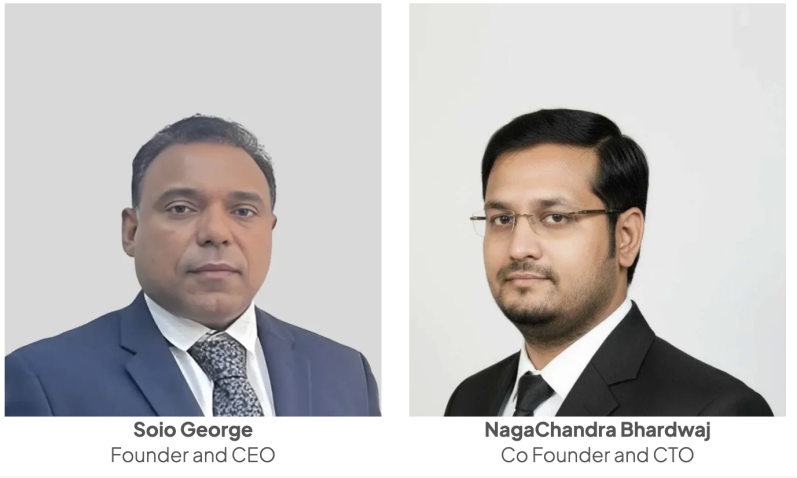
I3CGlobal and Reghelps SRC Collaborate to Deliver Comprehensive IVD Performance Evaluation Services for CE Marking

The partnership combines I3CGlobal's regulatory expertise with Reghelps SRC CRO's capabilities to streamline IVD Performance Evaluation and CE certification.



IVD Performance Evaluation

BANGALORE, KARNATAKA, INDIA, October 13, 2025 /EINPresswire.com/ -- I3CGLOBAL, a leading global regulatory consulting firm specializing in medical device and IVD compliance, has announced a strategic collaboration with Reghelps SRC CRO, a contract research organization specializing in clinical and analytical performance studies. The partnership aims to provide manufacturers with end-to-end support for IVD Performance Evaluation in line with EU Regulation (IVDR) 2017/746.

Together, I3CGLOBAL and Reghelps SRC (Research Collective Handling CRO) will deliver comprehensive solutions covering the Performance Evaluation Plan (PEP), Performance Evaluation Report (PER), Scientific Validity, Analytical and Clinical Performance Studies, and Post-Market Performance Follow-Up (PMPF). The collaboration ensures compliance with Annex XIII of the IVDR and readiness for Notified Body review.

> I3CGLOBAL partners with Reghelps SRC CRO to deliver IVDR Performance Evaluation services, combining regulatory and clinical expertise to accelerate CE Marking compliance."
>
> *Asha Johnson*

"Our collaboration with Reghelps SRC CRO enhances our ability to deliver technically sound and scientifically validated Performance Evaluation Reports that meet Notified Body expectations," said Asha Johnson, GM at I3CGLOBAL"

"By combining regulatory insight with our CRO's on-ground study execution expertise, we help clients accelerate IVDR certification," said by NagaChandra Bhardwaj, Director from Reghelps

SRC"

Under IVDR, manufacturers are required to demonstrate robust scientific validity, analytical performance, and clinical performance before CE marking. This partnership bridges the gap between regulatory documentation and real-world clinical data generation—enabling faster, compliant submissions and reducing review cycles.

Manufacturers seeking support for IVD Performance Evaluation and IVDR Technical Documentation can contact I3CGLOBAL

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