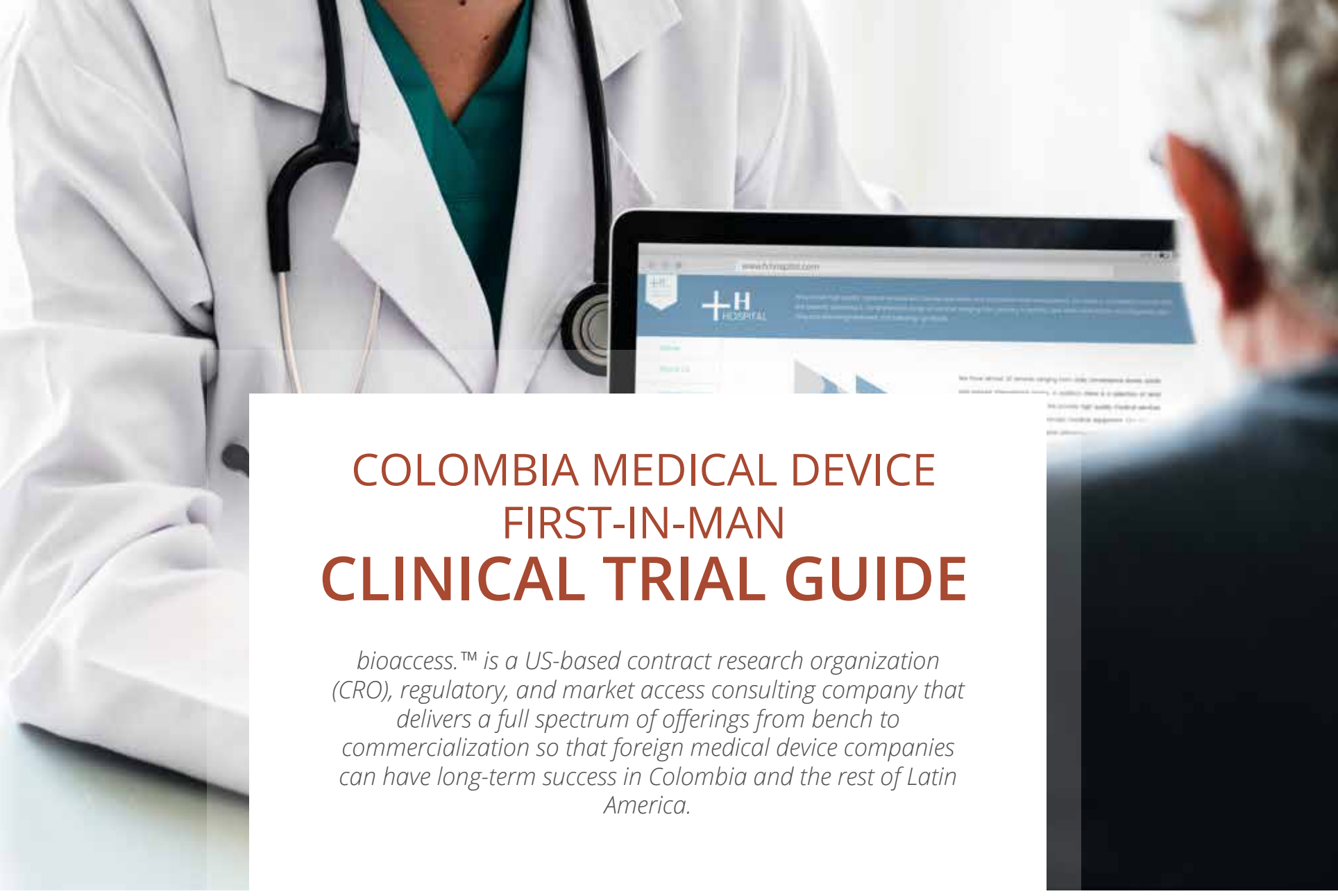

COLOMBIA MEDICAL DEVICE FIRST-IN-MAN
CLINICAL TRIAL GUIDE

bioaccess.™ is a US-based contract research organization (CRO), regulatory, and market access consulting company that delivers a full spectrum of offerings from bench to commercialization so that foreign medical device companies can have long-term success in Colombia and the rest of Latin America.

1 INSTITUTIONAL REVIEW BOARD (IRB/EC)

The research site's IRB or ethics committee (EC) needs to approve your study. You need to translate to Spanish your study documents and assemble a dossier package for submission. Meeting frequency is about every 30 days.

2 REGULATORY AGENCY (INVIMA)

You will need approval from Colombia's regulatory agency at the Ministry of Health (INVIMA). You need to translate your study documents to Spanish, put together a regulatory dossier package, and seek INVIMA approval to start recruiting patients and import your investigational medical device. INVIMA will review your application in about 30 days after submission.

3 IMPORT PERMIT, SHIPPING AND IMPORTATION

You will need an importation permit from the Ministry of Industry, Commerce and Tourism (MinCIT) before you ship your investigational device to Colombia (you will need a new import permit for every shipment). You need a local importer of record that can apply for the import permit on your behalf. All major shipping companies (Fedex, DHL, UPS) have direct 1-3 day service to Colombia. Processing time: Approximately 10 business days.

4 TRIAL BEGINS

You can now begin subject enrollment.

5 PROJECT AND DATA MANAGEMENT, MONITORING

You need to have a local CRO to professionally manage your trial to ensure protocol and regulatory compliance. The data collected during a clinical trial forms the basis of subsequent safety and efficacy analysis which in turn drive decision making on product development. Once subject enrollment begins, you need to ensure that data is collected, validated, complete, and consistent. You also need clinical and administrative oversight (aka study monitoring) to ensure the trial is being conducted according to plan.

6 STUDY CLOSURE AND CLINICAL STUDY REPORT

You need to submit a closure letter to the research site's IRB/EC. You need to file a study closure report with INVIMA. You need to return to your country of origin (or destroy) the inventory of all remaining investigational products that were not used during your trial. You will use the data gathered at the site in Colombia for your final study report (a detailed document outlining the methods and results of the trial). Results of trials are usually reported in an academic journal paper.

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