

ENSURE REGULATORY APPROVALS BY UNDERSTANDING GLOBAL CHALLENGES WITH HOME HEALTH VISITS

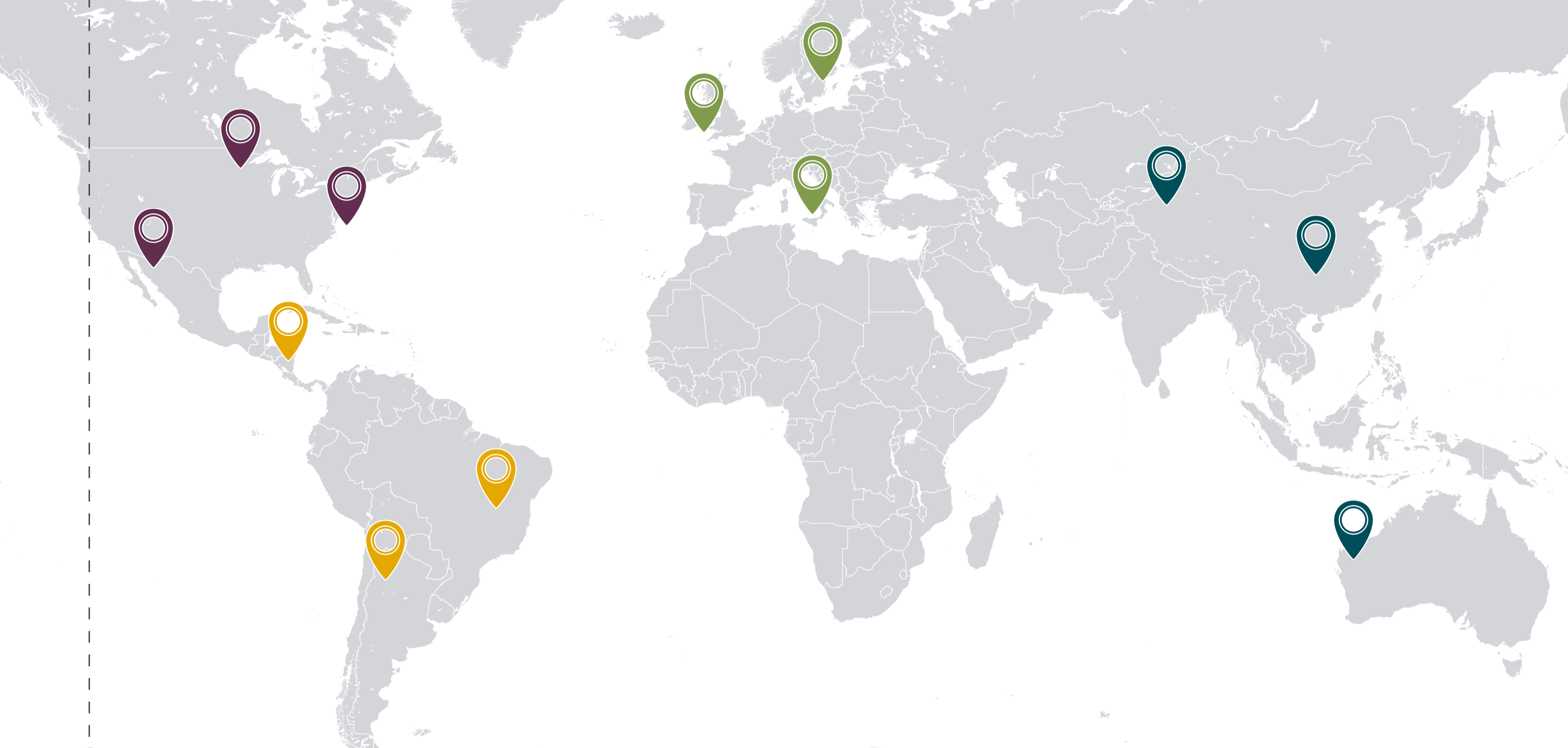
Incorporating home health visits is a valuable, patient-centric approach that can benefit your trials.

Enhance your clinical trial performance, improve data quality and ensure safety and efficacy by applying a patient-centric approach to patient visits.

However, when deploying global trials, there are country-specific challenges that must be proactively addressed to be successful.



Understanding cultural acceptance and regulatory climate



North America

- ▷ Home health visits widely accepted
- ▷ Significant population of home health care providers across region
- ▷ Few regulatory issues and limited local institution restrictions

Latin America

- ▷ Up-and-coming region for home health care
- ▷ Patient locations compared to provider availability can be challenging
- ▷ Challenging regulatory environment

Europe

- ▷ Home health visits widely accepted
- ▷ Home health care providers may have to travel great distances to reach patients
- ▷ Regulatory requirements can vary widely between Western and Eastern Europe

Asia Pacific

- ▷ Most countries (with the exceptions of Australia and New Zealand) have cultural norms preventing widespread adoption
- ▷ Limited regulatory issues in Australia or New Zealand

Addressing country-specific challenges



Asia Pacific

CHALLENGE:
Patient identifiers remain with country borders

SOLUTION:
Submit specific wording for EC approval



European Union (EU)

CHALLENGE:
Data privacy/protection

SOLUTION:
EU data protection requirements on data processors requires a Confirmatory letter to EU Ethical Committees



Spain

CHALLENGE:
Data privacy/protection

SOLUTION:
Incorporation of specific language in the ICF



Czech Republic & Bulgaria

CHALLENGE:
Home healthcare professionals' names and titles needed for EC submission

SOLUTION:
Pre-identify one or two providers per site



France & Germany

CHALLENGE:
The potential for long lead time for IDing and training provider

SOLUTION:
Obtain patient order at screening

3 WAYS TO ENHANCE YOUR GLOBAL TRIAL AND IMPROVE THEIR EXPERIENCE

Prepare now to successfully deploy a home health visit strategy in your global clinical trial.

What best practices can you follow to maximize your benefit from a patient-centric approach?

1

Incorporate RVS in your protocol

Differentiate from competitors by offering a more attractive solution to patients

2

Incorporate RVS into your IRB/EC strategy before approval

Save time and deployment costs by avoiding protocol deviations

3

Advance education and site communication

Incorporate site training, RVS attendance at IMs and SIVs, and include services in study newsletters and communications

Global patient visit experience you can count on

We provide the option for your global study subjects to complete selected visits at home, a convenient and comfortable location, increasing their potential participation in your trial regardless of study duration, frequency of visits, disease state, or distance to the study site.



HOME HEALTH VISITS IMPROVE THE EFFICIENCY AND PATIENT CENTRICITY OF YOUR GLOBAL TRIALS

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Improve quality data collection



Refine patient recruitment



Improve patient retention

WHY FIRMA RVS?

50+

years of collective home health visit experience

3,037

global home health visits completed

2,000

global home healthcare providers in database

REMOTE VISIT SERVICES

Enhance your trial. Improve their experience. Schedule a call with our RVS Leadership team for avv free protocol evaluation and feedback.

Email us at info@firmaclinical.com or visit firmaclinical.com.