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Clinical Investigators for PMCF studies

www.mantralink.com

The problem

- Medical device manufacturers increasingly required to conduct PMCF studies but often lack access to clinical sites.
- Clinical sites increasingly required to conduct research but study initiation / access slow and inefficient.
- Clinical studies can be a burden rather than a win-win.
- Outsourcing can be time consuming and expensive;
  regulatory red tape, barriers to progress, lack of support

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Unmet need

- Linking medical device manufacturers with a range of clinical investigation sites/investigators to perform PMCF tailored to their specific needs.
- PMCF study support for all PMCF activities related to a device.

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Our solution

Mantra Link
Doctors for Devices

- To create a network of pre-approved clinical sites where manufacturers and investigators can ‘link up’/form a partnership to run PMCF studies – with mutual benefits for both parties.

- Clinical sites would already be ready to run a trial, with a quick approval/onboarding process in place.

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What we can offer

- Linking manufacturers with clinical sites/investigators.
- Managing an agreement between clinical sites and manufacturers.
- Supporting manufacturers and clinical sites with the design, implementation and outputs of the studies.
- Facilitating in-house clinical investigation as a whole.

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Potential offerings

- Clinical Investigation Plan Writing
- Study design/Sample size calculation
- Study documents e.g., investigator brochure, study protocol, CRF, consent forms etc.
- Data collection platform/monitoring/SAE or AE reporting
- Data analysis (including interim results)
- Clinical Investigation Report writing

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Scope

Which studies?
Clinical investigations - Registry studies - Surveys

Which devices?
All device classes

Which regulatory frameworks?
EU/UK MDR - IVDR - FDA

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Manufacturer benefits

Pain Points - Lack of finance or workforce resources

Access to a network of pre-approved clinical investigators/sites

Choice of different study settings

Quick on-boarding (existing study frameworks in place)

All study activities taken care of

Cost effective

Time efficient

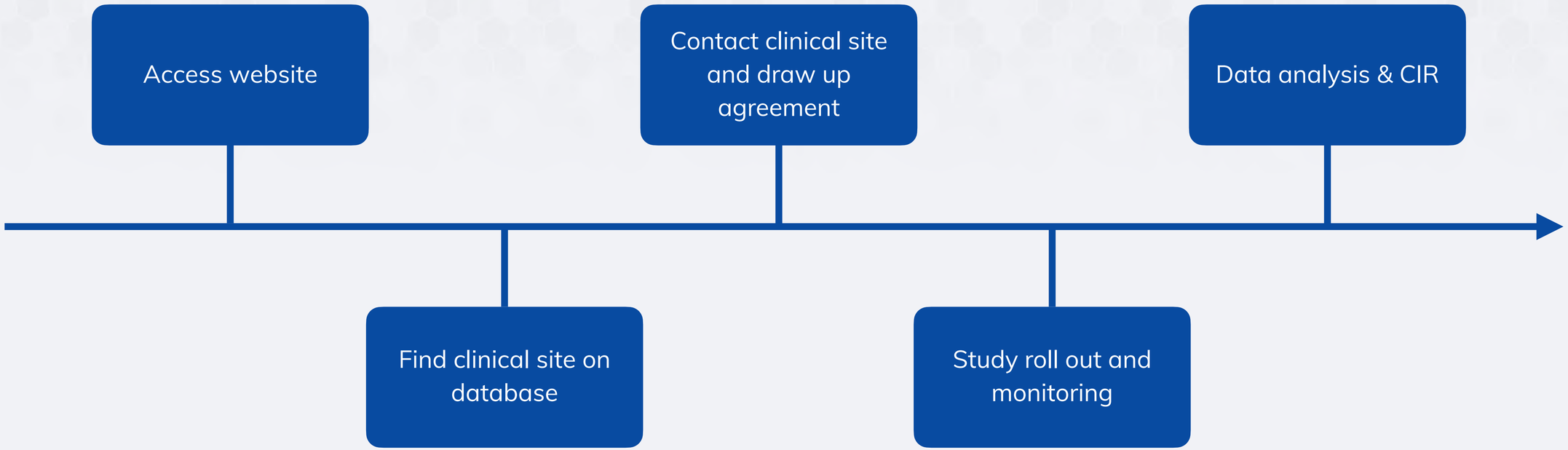
Clinical site benefits

Pain Points - Cost of trials, lack of research opportunities, little access to medical devices, regulatory/ethical barriers

- Research opportunities for junior doctors
- Easy access to a range of medical device manufacturers
- Device trials are relatively quick to perform
- Financial remuneration
- Clinical prestige
- Publications/ presentations
- Autonomy in delivering the studies

No costs or obligation to joint network!

Customer journey



Our vision

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Clinical Investigators for PMCF studies

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