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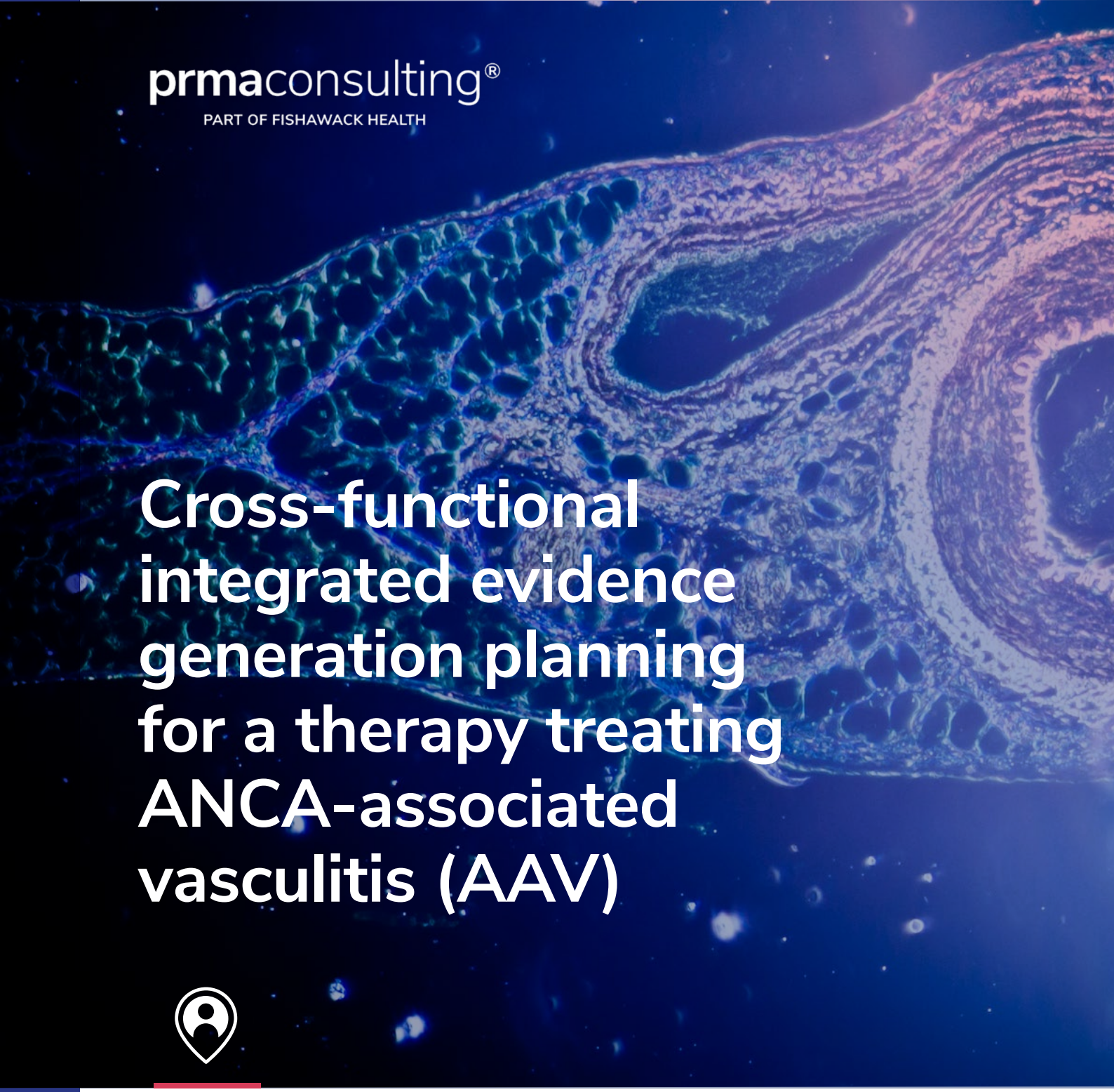

Cross-functional integrated evidence generation planning for a therapy treating ANCA-associated vasculitis (AAV)

SUMMARY

We conducted a cross-functional evidence gap analysis (medical, access, and commercial) and developed an evidence generation plan to support reimbursement activities.

OUR APPROACH

Assessment of the critical success factors across medical, market access, and commercial, as well as patient advocacy stakeholders

We identified the strategic success factors, value drivers, information needs, and research questions for the asset in AAV based on a review of client materials and one-to-one interviews with internal stakeholders (medical, market access, and commercial, as well as patient advocacy).

Facilitation of a workshop to achieve consensus on the evidence generation activities

Based on this assessment, value drivers and barriers were derived and presented at a half-day face-to-face workshop. During this workshop, consensus was reached on the key barriers and evidence generation activities required over the next 3 years. Evidence generation activities included activities beyond trial evidence, but excluded activities focused on communication and education.

Development of the integrated evidence generation plan

Following the workshop, an evidence generation plan was developed. This plan mapped all evidence generation activities to the key barriers identified, and included details on timing, feasibility, strength of the evidence, and impact on the value proposition for the asset.

Prioritization of evidence generation activities

This was taken further in a final prioritization session, where all evidence generation activities were categorized as high, medium, or low priority.

Evidence divers and barriers to secure optimal patient access and pull-through for Product X in line with commercial positioning

Evidence generation activities by barriers and time of read-out: low priority

Activity	Details	Barriers addressed	Timing	Feasibility	Strength of evidence	Impact on Product X value	Prioritization
RCT focused on long-term	→	B1 B2 B3	>3 years	▼	▲	▲	▼
Retrospective registry analysis	→	B3	<2 years	■	■	■	▼
Follow-up of trial cohort	→	B3	2-3 years	▼	▼	▼	▼
IIS to generate evidence on maintenance treatment within AAV	→	B1 B3 B6 B7	>3 years	▼	■	■	▼
Systematic literature review to highlight the mechanistic impact of MoA	→	B4	<2 years	▲	▼	▼	▼
Economic assessment based on data from trial and RWE	→	B8	2-3 years	■	▼	▼	▼
Matched control study using MAP data	→	B8	2-3 years	▼	▼	■	▼
Trial analysis to investigate speed of Product X' effect relating to QoL benefits over time	→	B2 B10	<2 years	▼	■	▼	▼

CLIENT VALUE

Detailed understanding of key value barriers gained from cross-functional assessment, including perspectives from medical, market access, and commercial teams.

Robust evidence generation plan that could be leveraged during internal stakeholder management, planning of activities, and assignment of accountable functions.

Foundation for yearly review and reprioritization

Both the key barrier assessment and the evidence generation plan can be evaluated on yearly bases, to add, remove, or reprioritize activities based on the changing needs for commercializing the asset.