

# Australian

# Regenerative Medicine

# Catalyst Body Funding

# and Model Structure

Prepared by Research Strategies Australia



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## Foreword

The Regenerative Medicine Catalyst Project has brought together seven partners in a consortium to build the foundations for a national regenerative medicines (RM) sector ‘catalyst’ collaboration body. The Regenerative Medicine Catalyst Project will address priority action areas including: workforce capabilities, collaboration, funding, regulation and policy infrastructure, and Australian manufacturing capability. The Catalyst Consortium and the subsequent Catalyst Body aim to support the Australian RM industry to see it thrive and drive benefits to the health of its people and Australia’s economy. This Australian Regenerative Medicine Catalyst Body Funding and Model Structure report forms a key part of the Regenerative Medicine Catalyst Project.

The significance and need for the Regenerative Medicine Catalyst Project was highlighted in a national, sector-wide report that assessed the current state of the Australian RM sector and made recommendations on the priorities and goals, see Regenerative Medicine: Opportunities for Australia (MTPConnect, LEK, 2018).

Major outcomes of the project include other reports and data that each add further to the body of evidence and understanding of the sector. The reports include:

- A researched, strategic roadmap for the RM sector’s development in Australia, including sub-reports on skill and talent specific to the sector, determining a plan to attract patient venture capital investment and the role of Australian biotech companies partnering with global companies, and case studies;
- (This report) Determining a sustainable funding and model structure for an RM sector ‘catalyst’ collaboration body;
- A regulatory white paper;
- Establishing annual data points and information resources to: map/benchmark GMP manufacturing capability and capacity, establish a model for an annual clinical trial database; and capture investments in Australian RM;
- Mapping the pathway for a typical product from early research to market, and patients receiving a therapy; and
- Mapping the global pipeline of gene and cell therapy products on the horizon.

## Context

Australia has an opportunity to harness and leverage a growing and active global RM industry. If we get this right, success could be worth at least \$6 billion (B) in annual revenue, 6,000 new jobs for Australia by 2035 and earlier access to ground-breaking therapies for Australian patients<sup>1</sup>.

RM is a multidisciplinary field that seeks to develop the science and tools that can help repair, augment, replace, or regenerate damaged or diseased human cells, tissues, genes, organs, or metabolic processes, to restore normal function. It may involve the transplantation of stem cells, progenitor cells, or tissue, stimulation of the body's own repair mechanisms, or the use of cells as delivery vehicles for therapeutic agents such as genes and cytokines.

RM includes gene therapies, cell therapies, and tissue-engineered products intended to regenerate or replace injured, diseased, or defective cells, tissues, or organs to restore or establish function and structure.

Globally, the growing sector has more than 1,200 clinical trials in progress and attracted about AU\$26.3B (or US\$19.9B) in financing in 2020<sup>2</sup>. With 97 ongoing RM Phase III clinical trials or products awaiting regulatory decisions in the coming months, therapeutics companies are turning their attention to the RM sector<sup>3</sup>.

There are also increasing numbers of gene and cell therapies being developed in and brought to Australia for patient access.

Australia has a strong and active RM industry eco-system with basic and translational research capabilities, a clinical trials framework and clinical centres that are all internationally-recognised. More than 60 companies in Australia are developing RM products and more than 130 clinical trials in progress<sup>4</sup>.

## Introduction

This report provides a recommendation for a funding and model structure for the Regenerative Medicine (RM) sector ‘catalyst’ collaboration body, with a scope that includes industry as a key component within a broader sector.

This report includes both the recommendation for the funding and model structure and the detailed analysis used to determine the sustainable funding and model structure for a RM sector ‘catalyst’ collaboration body. The analysis includes detailed research into models that are used for similar purposes in other sectors.

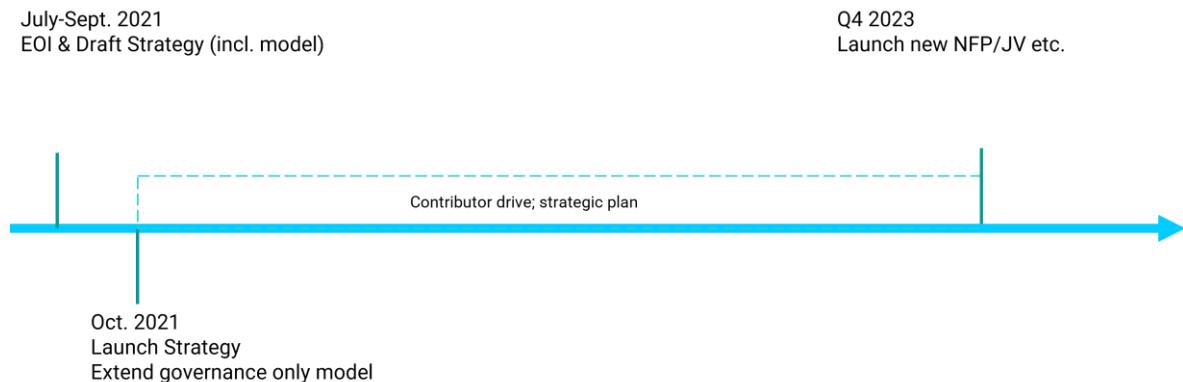
## Recommendation for Regenerative Medicine ‘Catalyst’ Collaboration Body

It is recommended that:

AusBiotech and Medicines Australia to co-lead work to establish a Catalyst that will take the place of the Consortium at the end of the RM Catalyst Project (30 September 2021) and seek to derive further value and development from the Consortium’s work on the RM Catalyst Project.

- Between now and September 2021, an Expression of Interest (EOI) be undertaken by AusBiotech and Medicines Australia to identify contributors to the Catalyst.
- The EOI seek three levels of interest:
  - Financial contributors willing to provide financial support to the Catalyst;
  - In-kind contributors willing to take a leading role in the Catalyst (i.e. governance, leadership, provide office space, legal and secretariat support); and
  - Other parties interested in participating in the activities of the Catalyst.
- From 1 October 2021, the Consortium be ended in its current form, and the Catalyst be formed by ‘Charter’ amongst its financial and in-kind contributors. The Charter is to determine the governance and decision-making structures. AusBiotech and Medicines Australia to provide in-kind support until adequate funding can be secured.
- When adequate funding is secured, the Catalyst undertake a search to recruit a senior executive to the role of General Manager (GM) (or equivalent) for the Catalyst, whose salary is paid from the funding obtained for the Catalyst.
- The Catalyst develop a position description and key performance indicators for the GM that include obtaining additional funding for the Body to be financially viable within two (2) years of 1 October 2021.
- Within two years of 1 October 2021, the Body determine the optimal option between establishing a permanent joint venture (JV) or a new not-for-profit (NFP) as a vehicle for the Catalyst, see Figure 1.

## Figure 1: Recommended timing



## Analysis of funding and structure models

### Background

In recognition of the ongoing growth in the RM sector both in Australia and globally, AusBiotech established a Regenerative Medicine Advisory Group in 2016 to:

- provide advice on current and emerging issues and trends facing the RM sector in Australia and overseas;
- improve and engage the sector;
- generate a clear definition of RM; and
- address key advocacy issues.

The group worked with MTPConnect to develop a national, sector-wide report, *Regenerative medicine: Opportunities for Australia* (MTPConnect, LEK, 2018)<sup>5</sup>, to assess the current state of the Australian RM sector and make recommendations on the priorities and goals for the sector. Amongst the report's recommended next steps is: identifying and establishing the national RM sector 'catalyst' collaboration body (the Body).

This report, commissioned as part of the Regenerative Medicine Catalyst Project provides a recommendation for a funding and model structure for the RM sector 'catalyst' collaboration body.

The recommendation was developed as follows:

- Detailed analysis of financial models and structures of existing bodies internationally in the RM sector;
- Consideration of examples from 'outside' the RM sector and;
- Consultations with and surveys of the Regenerative Medicine Catalyst Project consortium members.

This report provides a summary of the findings from this approach and guidance for the recommendations for establishing a catalyst body.

### International RM Organisations

As the RM sector grows internationally, the number and nature of groups involved in representing and growing the sector increases. These range from global organisations such as the Alliance for Regenerative Medicine (ARM) – the leading international advocacy organisation dedicated to realising the promise of regenerative medicine and advanced therapies – through to national initiatives such as the Cell and Gene Therapy Catapult – which helps cell and gene therapy organisations translate early-stage research into commercially viable and investable therapies.

There is no one approach to catalysing a RM sector. In some jurisdictions the focus is largely on creating regulatory conditions favourable to the development of the RM sector – as is the case with the Forum for Innovative Regenerative Medicine (FIRM) in Japan. In others, the focus is on funding RM research – as is the case of the California Institute of Regenerative Medicine (CIRM) which disburses the proceeds from the general obligation bonds issued by the state of California to fund stem cell research.

Nor is there one player in any jurisdiction that is acting alone to do this – be it industry, government or non-profit organisations. Instead, the current international approach is comprised of multiple public, private and non-profit participants working collaboratively to drive the growth of the RM sector in any jurisdiction.

Even where these efforts are largely funded from a single source – for example the California Institute of Regenerative Medicine (CIRM) or the Council for Advanced Regenerative Medicine (CARM) in Korea, both of which are government funded – their purpose is to catalyse an entire sector and not just one set of actors in it (e.g. not only public research labs but also private sector research labs).

As a result of both the breadth of participants and breadth of missions there is also a breadth of financial models. However, these can be grouped into two primary models – government funded or membership-based. So, for example, ARM and FIRM derive their revenues largely through membership fees and offer a range of tiered memberships, in the case of ARM, tied to company financial turnover. Catapult, CARM and CIRM are all largely funded through government sponsorship, though through different mechanisms e.g. CIRM is funded via bonds, CARM effectively acts as a part of government and Catapult is formed as an independent non-profit but funded from government.

Table 1 Selected international RM bodies

Organisation	Purpose	Model
The Alliance for Regenerative Medicine (ARM; global)	Promotes legislative, regulatory and reimbursement initiatives	Independent non-profit Membership-based (~360 members)
Cell and Gene Therapy Catapult (UK)	Technology and innovation centre connecting businesses with the UK's research and academic communities to translate early-stage research into investable therapies	Independent non-profit Funded from a mix of commercial funding and core Innovate UK Government investment
California Institute of RM (CIRM; USA)	Disbursing the proceeds from the general obligation bonds issued by the state to fund stem cell research in California	Government Primarily funded through the state of California through bond issues
Forum for Innovative RM (FIRM; Japan)	Accelerating research and commercialisation of regenerative medicine	Incorporated association Member based (~270 members)
Council for Advanced Regenerative Medicine (CARM; Korea)	Expand investment opportunities for RM companies Expand overseas networks and cooperation Develop industrial policies through legal systems, industrial promotion, and insurance benefits and policies	Government

## Purpose of a catalyst body

Each RM body is set up with a unique purpose, and from this the various models follow. For example, FIRM in Japan is charged with the purpose of accelerating research and commercialisation of regenerative medicine in Japan, and as such, is largely industry focused. FIRM's purpose<sup>5</sup> is to pave the way for practical breakthroughs in RM by:

- pursuing broad, industry-led partnerships with governments, universities, and the private sector;
- engaging with the media and building consensus on the application of RM in the community;
- taking a big-picture view of the process of clinical research, approval, and worldwide promotion of RM from the perspective of business development and industrialisation of RM; and,
- being a think tank for innovation in the RM field.

This informs both their legal model – they are an incorporated association – as well as their business model, which derives revenue from membership by industry-based members.

By contrast the Cell and Gene Therapy Catapult in the UK is part of the broader Catapult network established by Innovate UK to support innovation by UK business. They form a network of technology and innovation centres established as independent non-for-profit private organisations aimed at transforming the UK's capability for innovation in designated sectors. Catapults are effectively technology and innovation centres connecting businesses with the UK's research and academic communities providing businesses access to technical facilities and expertise.<sup>6</sup>

As a result of significant government investment, the Cell and Gene Therapy Catapult has invested in significant shared infrastructure including a 1200sqm development centre in London and a £55 million manufacturing centre in Stevenage. This is a case of government stepping in to underwrite the future success of the sector and investing heavily.

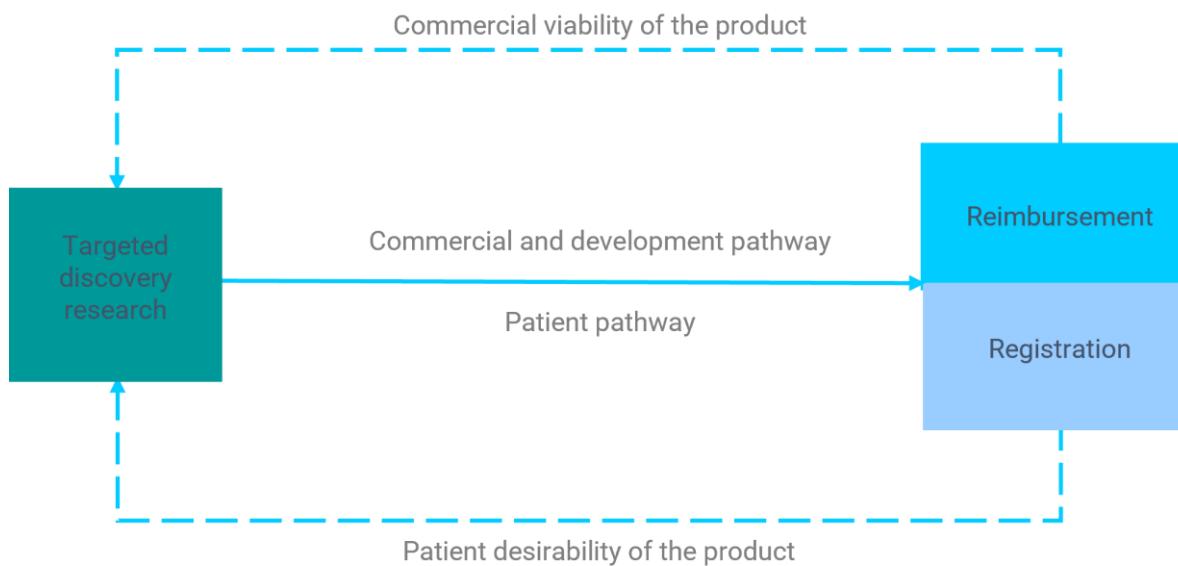
In both cases above, different though they are, there is a strong focus of the development of the RM sector from the point of translation onwards.

In consultations with various stakeholders in the Australian setting, the need for a body that is focused on the process from the point of translation onwards was also clearly articulated. However, it was also widely accepted that, at this nascent stage of the development of the sector, that a catalyst body should aim to cover the entire value chain from discovery through to patients.

## Scope of a catalyst body

In order to balance priorities, a catalyst body will need to encompass the entire RM value chain in scope, but with a distinct industry focus (Figure 2). The RM value chain is diverse, and presents unique challenges not apparent in other therapies e.g., there are unique storage and transportation challenges, unique manufacturing challenges, unique patient challenges like proximity to treatment sites etc. However, from the perspective of having a successful RM industrial capability in Australia, there are two fundamental challenges that affect all aspects of the RM value chain – if a therapy cannot be registered and/or reimbursed there will not be a RM sector.

**Figure 2: Proposed scope of RM Catalyst Body**



There are two corresponding pathways – one corresponding to the existence of patients to receive a therapy (the ‘patient pathway’) and one corresponding to the commercial opportunity presented by a therapy (the ‘commercial and development pathway’). While there are many complex processes and actors across the RM value chain, each one can be situated across one or both of these pathways.

For example, manufacturing capability is fundamental to a successful RM sector, however, it is a consideration along the ‘commercial and development pathway’ e.g. How much would it cost to manufacture this therapy? It therefore leads into considerations of questions around reimbursement.

Similarly, patient access to therapies is fundamental to the development of the RM sector, but fits along the ‘patient pathway’ and leads to the considerations around registration. It also feeds into questions around reimbursement.

As outlined, it is important for a catalyst body to reflect the entire RM value chain, and this includes discovery-based research. To accommodate this within the industry focus of the catalyst body, Figure 2 includes two feedback loops that are used to inform what discovery-based research is included and excluded from its remit: discovery research is within the scope of the catalyst body where it is informed by considerations of commercial viability or patient desirability. This will leave a proportion of discovery research out of scope – however, discovery research is well supported by existing infrastructure, and, at such a time as discovery projects are informed by commercial viability and/or patient needs it will fall within the scope of the catalyst body.

## Function of a catalyst body

Throughout interviews with stakeholders a range of different functions have become apparent. These resonate with the existing and well-established role of a ‘backbone’ organisation from the collective impact movement.<sup>7</sup> This is not surprising given the similarities between the collective impact movement and the issue of fostering and growing the RM sector in Australia – there is a diverse group of actors from different sectors (manufacturing, pharmaceutical companies, biotech companies, patient groups, transport and storage companies, clinicians, governments etc.) with a common agenda looking to solve a complex set of issues.

As such, a modified version of function of a ‘backbone’ organisation can serve as the basis for the RM catalyst body. This would include the following functions:

### ***Guide vision and strategy***

- Build a common understanding of the opportunity for the RM sector
- Serve as a thought leader/standard bearer for the RM sector
- Ensure common agenda is updated as needed as strategy unfolds

### ***Advance policy***

- Advocate for an aligned policy agenda
- Stay on top of policy developments that impact the RM sector to establish and grow the sector

### ***Mobilise resources***

- Mobilise and align public and private resources to support the RM sector

### ***Build community engagement***

- Create a sense of urgency and articulate a call to action
- Support community member engagement activities
- Produce and manage communications

### ***Establish shared measurement practices***

- Collect, analyse, interpret and report data
- Catalyse or develop shared measurement systems
- Provide technical assistance for building partners' data capacity

### ***Support aligned activities***

- Coordinate and facilitate partner's continuous communication and collaboration (e.g. meetings)
- Recruit and convene partners and external stakeholders
- Seek out opportunities for alignment with other efforts
- Ensure taskforces are being data driven

While the development of a strategic roadmap for the RM sector is due in 2021 and will include a range of detailed actions for fostering and growing the RM sector, the 2018 report from LEK and MTPConnect has already identified a range of activities that will likely be included. A survey of the consortium members from the Regenerative Medicine Catalyst Project about: (i) the impact of the activity on the RM sector, (ii) the complexity to deliver the activity and (iii) the timing of each activity (short, medium or long term to achieve) assists in thinking through the function of a catalyst body. The results are presented in Table 2. What is clear is that there are different ways that a catalyst body could seek to develop the RM sector in Australia. For example, there are outcomes that would be relatively low complexity such as establishing a disease team-based approach or effectively targeting funding from the Medical Research Future Fund (MRFF) to build the RM sector.

Alternatively, there are a range of outcomes that could be delivered quickly, such as further developing world-leading training programs, continuing/increasing financial incentives that encourage RM operations in Australia, supporting a nationally focused commercialisation hub and effectively targeting funding from the MRFF to build the RM sector.

Finally, many of the outcomes would be high impact, including: continuing/increasing financial incentives that encourage RM operations in Australia; increasing resources to expedite translational research; supporting a nationally focused commercialisation hub; establishing a disease team-based approach; effectively targeting MRFF funding to build the RM sector; encouraging investment through alignment of sector activities with government priorities; attracting private investment and international VC; harmonising regulation with leading global markets; extending pharmaceutical accelerated approval pathways to biologicals; and, providing a clear path to market access and broaden scope for reimbursement.

This is not an exhaustive list of the activities and outcomes that a catalyst body would work towards. However, across these and other activities a catalyst body should function to Guide vision and strategy, Advance policy, Mobilise resources, Build community engagement, Establish shared measurement practices and Support

aligned activities. And this should be done within the scope of being industry led and guided by a framework that considers the end points of reimbursement and/or registration as overarching goals.

Table 2 RM sector activities survey results, survey of Regenerative Medicine Catalyst Project consortium members

Activity	Impact*	Complexity*	Timing*
Capabilities/Workforce: Further develop world-leading training programs	2	2	1
Capabilities/Workforce: Continue/increase financial incentives that encourage RM operations in Australia	3	2	1
Capabilities/Workforce: Increase resources to expedite translational research	3	2	2
Collaboration: Support a nationally-focused commercialisation hub	3	2	1
Collaboration: Establish a disease team-based approach	2	1	2
Funding: Effectively target MRFF funding to build the RM sector	3	1	1
Funding: Encourage investment through alignment of sector activities with government priorities	3	2	2
Funding: Attract private investment and international VC	3	2	3
Regulation and Policy: Harmonise regulation with leading global markets	3	2	2
Regulation and Policy: Extend pharmaceutical accelerated approval pathways to biologicals	3	2	2
Regulation and Policy: Provide a clear path to market access and broaden scope for reimbursement	3	2	2
Infrastructure: Actively pursue and encourage opportunities to build and/or attract flexible and commercially viable manufacturing capability	2	2	2

\*Impact: 1 = Low, 2 = Medium, 3 = High

Complexity: 1 = Low, 2 = Medium, 3 = High

Timing: 1 = Short term, 2 = Medium term, 3 = Long term

## Models for a Catalyst Body

The governing and financial model for a catalyst body is directly influenced by its scope and function. These have both been considered in detail in the previous section. Both are forward looking constraints asking *What is the destination?* However, a catalyst body is also influenced by the current state and the resources available as inputs and these need to be factored into its design.

While Australia has a strong and active RM sector with more than 60 companies in Australia developing products and more than 130 clinical trials in progress, combined with strong basic research capabilities, it is a small and nascent sector. As such, some financial models are not immediately practical, such as a model dependent on a large membership base. In the future this is likely to be a viable model, but for the time being it is not.

With that said, however, the international RM sector is growing rapidly, and this has implications for Australia. At the time of this report, there are over 1,200 clinical trials in progress and 97 ongoing RM Phase III clinical trials or products awaiting regulatory decisions in the coming months.<sup>8</sup> This means that a model must be fit for purpose for the present sector as well as, in all likelihood, a vastly larger sector in the short- to medium-term.

There are a range of options available to deliver a catalyst body that are more or less suited to the current and future needs. These are presented in Table 3<sup>9</sup>, alongside some of the overarching considerations for and against each model. For example, establishing a catalyst body within an existing non-profit organisation can provide a high degree of credibility, clear ownership, and strong understanding of the issues by leveraging the expertise and capability of the existing organisation and will also benefit from existing infrastructure that may not be otherwise available to a new venture. It also suffers from perceptions of ‘baggage’ and issues around independence and neutrality.

Table 3 Catalyst body organisation types

Type of org.	Funder	Pros	Cons
Funder-Based	One funder initiates the strategy as planner, financier, and convener	Ability to secure start-up funding and recurring resources Ability to bring others to the table and leverage other funders	May lack broad buy-in if effort is seen as driven by one funder Potential perceived lack of neutrality
New Non-profit	New entity is created, often by private funding, to serve as catalyst body	Perceived neutrality as facilitator and convener Potential lack of 'baggage' Clarity of focus	Lack of sustainable funding stream and potential questions about funding priorities Potential competition with local nonprofits Cost of independent operations (e.g. insurance, office space, governance, etc.)
Existing Non-profit	Established non-profit takes the lead in coordinating strategy	Credibility, clear ownership, and strong understanding of issue Existing infrastructure in place if properly resourced	Potential 'baggage' and lack of perceived neutrality Lack of attention to the initiative if poorly funded
Government	Government entity, either at local or state level, drives the effort	Public sector 'seal of approval' Existing infrastructure in place if properly resourced	Bureaucracy may slow progress Public funding may not be dependable
Shared Across Multiple Organisations	Numerous organisations take ownership of the initiative	Lower resource requirements if shared across multiple organisations Broad buy-in, expertise	Lack of clear accountability with multiple voices at the table Coordination challenges, leading to potential inefficiencies
Organisation of Organisations	Senior-level committee with ultimate decision-making power	Broad buy-in from senior leaders across public, private, and nonprofit sectors	Lack of clear accountability with multiple voices

At present, it is important to note that several of these options are ‘off the table’, at least for the time being: there is no indication from government at any level that they are willing to catalyse the RM industry in the manner of, say, the Cell and Gene Therapy Catapult (UK), or CARM (Korea); nor has a funder stepped forward to fulfill the role of the State of California in the case of CIRM (USA); and, finally, given the breadth of the RM value chain, it is unlikely that any single existing organisation would be able to absorb the significant agenda into their existing resource base.

This leaves the options of structuring a catalyst body as either a new non-profit entity, sharing the catalyst body across multiple existing organisations or establishing a layer of shared governance across multiple organisations without establishing a separate entity.

The case for and against each of these three is explored in more detail below. This draws from the background literature on collective impact initiatives as well as consultations undertaken as part of this project.

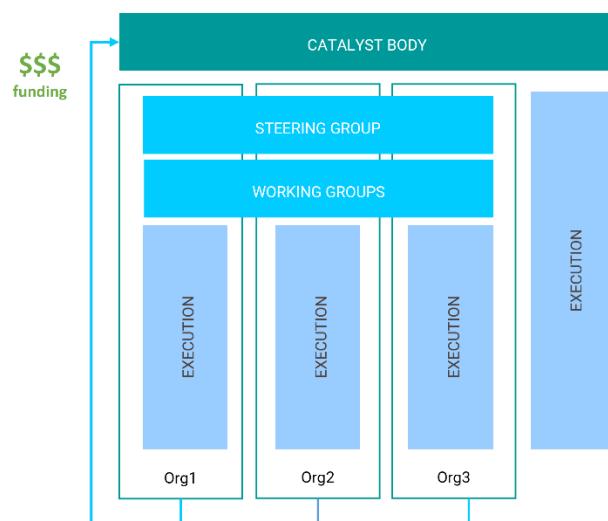
### New non-profit (NFP)

Establishing the catalyst body as a new non-profit would allow for a board of directors with a clear governance structure and accountabilities. A board of directors would also assume all of the risk associated with the organisation including financial oversight and hiring and firing decisions. As a charitable organisation it would also be eligible for a number of grant funding opportunities.

A new entity would allow for the mission and vision to be closely aligned with its board of directors, and it would benefit from perceptions of neutrality and independence.

As a new entity, it would not have any existing infrastructure and would need to develop and pay for accounting, back office, insurance, governance and other capabilities for itself, which can be costly and divert funding and energy from the mission. It may also give the impression that the organisation is in competition with other organisations that would otherwise be collaborators or partners.

**Figure 3: New non-profit entity example**

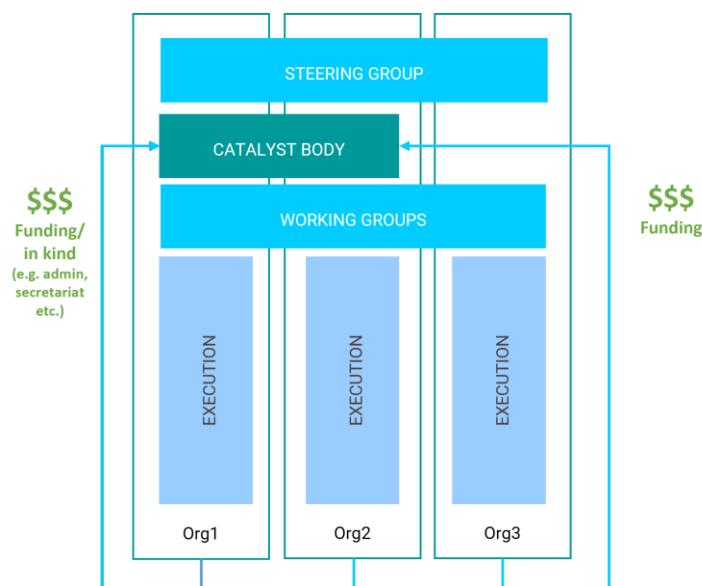


## Shared across existing non-profits – Joint Venture (JV)

Sharing the responsibilities of a catalyst body across one or more existing organisations has the advantage of drawing on the leadership, expertise, experience, networks and infrastructure of multiple existing organisations. This frees up resources to dedicate to mission. It also means that multiple leadership teams are engaged deeply with the organisation from the outset and mitigates against perceived lack of neutrality or independence. Risk is also shared across a variety of organisations such that no single organisation assumes all the financial and legal risk.

In following this path, however, it is important that there is clarity amongst participants as to roles and responsibilities. This will help with avoiding confusion for staff about who is accountable to whom or which organisation for what deliverables and activities. This structure also increases the potential for conflicts between organisations, and the potential for duplication of effort across organisations. A high degree of collaboration is required to make this work.

**Figure 4: Shared across existing non-profits example**

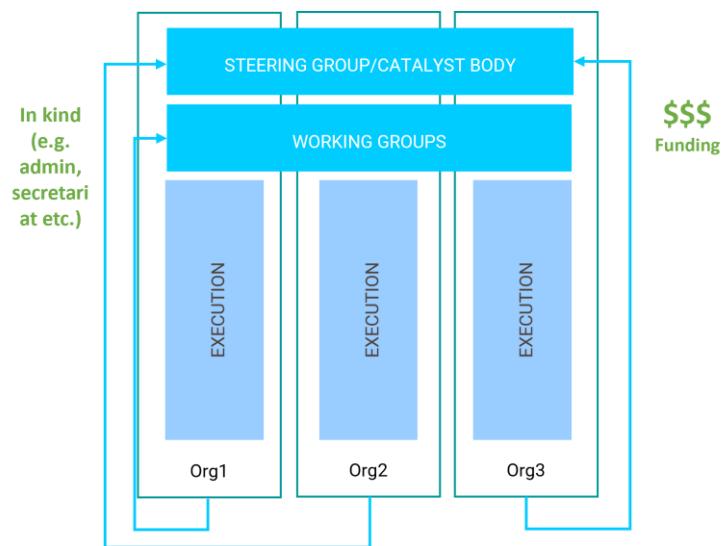


## Organisation of organisations - Governance only

Undertaking a catalyst body as solely a governance exercise is the simplest approach in principle. It requires no infrastructure and could be developed as simply as with a MOU between organisations.

It benefits from deep engagement with leadership from multiple organisations and the functional aspects of the delivery can be shared across multiple organisations. Similarly, risk is shared across a variety of organisations such that no single partner assumes all the risk. Without dedicated resourcing, however, this approach runs the risk of the catalyst body becoming a side projects relative to each organisation's own priorities. There is also a high risk of conflicts emerging between organisations where workloads are being distributed unevenly. Finally, there is likely to be a lack of accountability in this approach as nobody assumes responsibility for the success or failure of the catalyst body's activities. This option would work best with a dedicated leader/general manager.

**Figure 5: Organisation of organisations**



## References

<sup>1</sup> MTPConnect, LEK Consulting. (2018). *Regenerative Medicine - Opportunities for Australia*

<sup>2</sup> 2020: Growth & Resilience in Regenerative Medicine, Annual Report Cell & Gene State of the Industry Briefing, Alliance for Regenerative Medicine, 2021

<sup>3</sup> 2020: Growth & Resilience in Regenerative Medicine, Annual Report Cell & Gene State of the Industry Briefing, Alliance for Regenerative Medicine, 2021

<sup>4</sup> Regenerative Medicine Catalyst Project. (2021). Australia's Regenerative Medicine Clinical Trials Database.

<sup>5</sup> MTPConnect, LEK Consulting. (2018). *Regenerative Medicine - Opportunities for Australia*

<sup>6</sup> <https://catapult.org.uk/>

<sup>7</sup> Modified from [https://ssir.org/articles/entry/collective\\_impact](https://ssir.org/articles/entry/collective_impact)

<sup>8</sup> 2020: Growth & Resilience in Regenerative Medicine, Annual Report Cell & Gene State of the Industry Briefing, Alliance for Regenerative Medicine, 2021

<sup>9</sup> <https://www.collectiveimpactforum.org/resources/backbone-starter-guide-summary-major-resources-about-backbone>



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