




Developing the FOP Australia Advocacy Strategy

Aims

- A major aim of FOP Australia is to do whatever possible to help make an effective and safe treatment for FOP available in Australia and New Zealand as soon as possible.
- The aim of this document is to articulate the steps in this process for our community, supporters and board to guide FOP Australia's activities



What steps need to happen for an
FOP therapy to be available in
Australia and New Zealand?



1

Evidence that a drug works



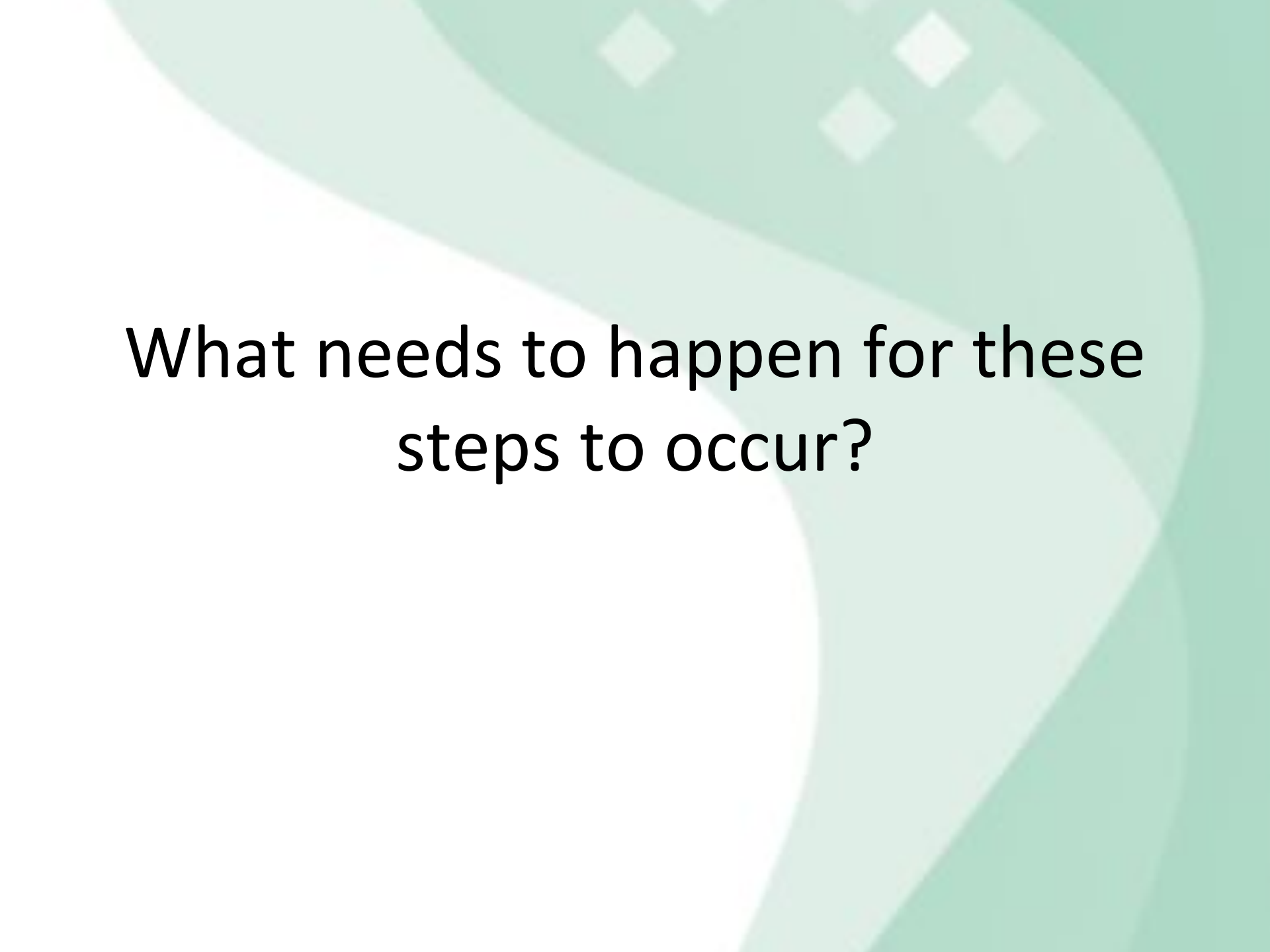
2

A drug is approved as being safe for use (TGA)



3

The cost of a drug is subsidised by the government (PBAC)



What needs to happen for these
steps to occur?

1

Evidence that a drug works

Understanding of the disease

Successful clinical trials

2

A drug is approved as being safe for use (TGA)

Review of trial outcomes by TGA

Orphan drug designation

3

The cost of a drug is subsidised by the government (PBAC)

Cohesive community advocacy

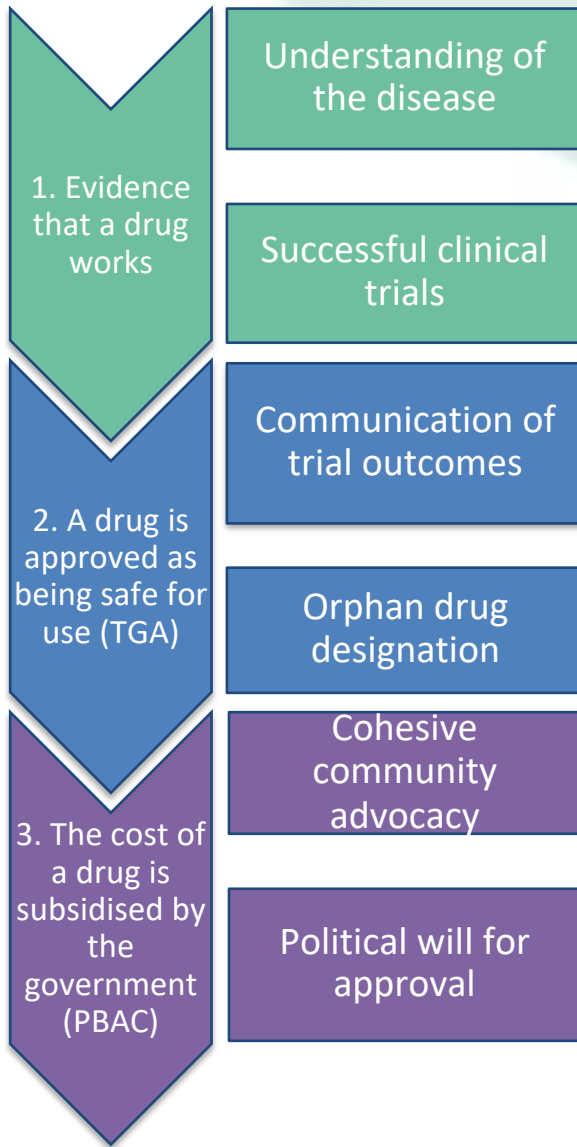
Political will for approval



How can we make that happen?

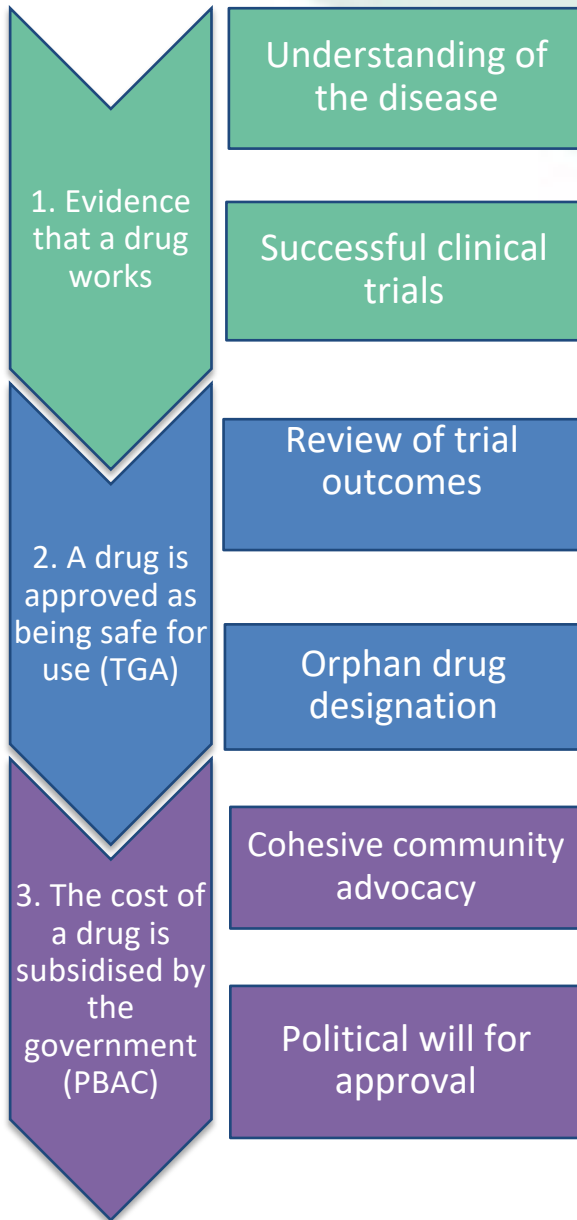
Drug development and approval process:

Actions required:



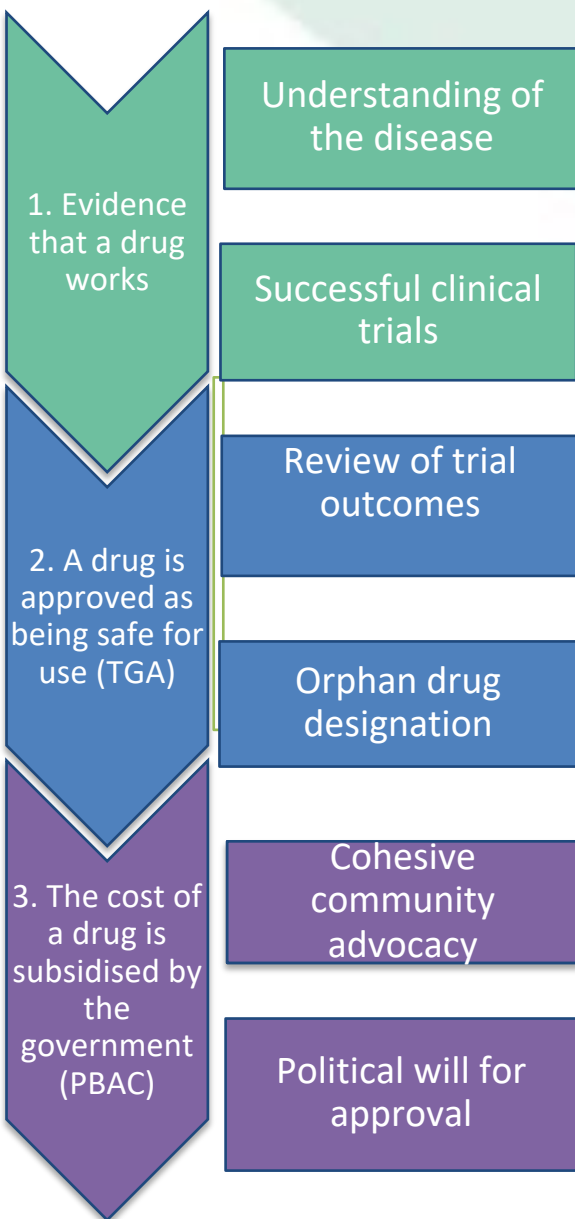
Drug development and approval process:

Actions required:

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Drug development and approval process:

Actions required:



Global knowledge	Community awareness topics	Relationships	Tools/deliverables	Infrastructure
Understanding of disease mechanisms	-New FOP insights -Drug development process including pharma -Role of registry	-Researchers -Pharma and biotechnology companies	-Maximised use of tissue samples from community - Registry participation	-Fundraising for research - Dedicated liaison officers for drug companies
-Data from a successful phase 3 trial	-Clinical trials -Factors to consider when deciding to enter a trial	-Clinicians -Pharma and biotechnology companies -Researchers	-Trial participation	-Regular communication with FOP families -Regular communication with clinicians
	-TGA process - Medicines access programs (MAPs)	-Clinicians -Pharma and biotechnology companies	-Access to drugs via MAPs whilst awaiting PBAC approval	
	-Orphan drug designation	- Rare Voices Australia (RVA)	-RVA work on Rare Disease Strategy	
	-Principles of effective lobbying -Upskilling of patient advocates	-RVA -IFOPA	- Preparation notes and info sessions for patient advocates	-Ongoing participation of families in organisation -Organisational integrity
	-PBAC process (including appeal)	-Politicians and policymakers	-Demonstrable supporter base (membership/supporter numbers) -Printed materials, speech notes, online	-Fundraising to fund lobbying materials -Fundraising to fund in person lobbying of politicians



Summarising these steps:

List of actions

- Build community awareness of key topics:
 - Understanding of FOP (inc new FOP insights)
 - Clinical trials
 - Factors to consider when deciding to enter a trial
 - TGA process
 - Medicines access programs (MAPs)
 - Orphan drug designation
 - Principles of effective lobbying
 - Upskilling of patient advocates
 - PBAC process (including appeal)
- Build relationships:
 - Clinicians
 - Pharma and biotechnology companies
 - Researchers
 - Rare Voices Australia (RVA)
 - IFOPA
 - Politicians and policymakers
- Deliverables/targets:
 - Utilisation of tissue samples in research
 - Registry participation
 - Trial participation
 - Access to drugs via MAPs whilst awaiting PBAC approval
 - RVA work on Rare Disease Strategy
 - Preparation notes and info sessions for patient advocates
 - Demonstrable supporter base (ie. membership and supporter numbers)
 - Clear messaging on printed materials, speech notes, online
- Maintain infrastructure to support process:
 - Fundraising to support research
 - Dedicated liaison officers for clear communication with industry companies
 - Regular communication with FOP families
 - Regular communication with clinicians
 - Ongoing participation of families in organisation
 - Organisational integrity
 - Fundraising to fund lobbying materials (and travel for direct lobbying of decision makers during government review process)



Or to organise that differently...

Our advocacy strategy is to build:

- Our knowledge
- Our relationships
- Our results
- Our strength

Our knowledge

- **Build community awareness of key topics:**
 - Understanding of FOP (inc. new insights)
 - Clinical trials
 - Factors to consider when deciding to enter a trial
 - TGA process
 - Medicines access programs (MAPs)
 - Orphan drug designation
 - Principles of effective lobbying
 - Upskilling of patient advocates
 - PBAC process (including appeal)

Our relationships

- **Build relationships:**
 - Clinicians
 - Pharma and biotechnology companies
 - Researchers
 - Rare Voices Australia (RVA)
 - IFOPA
 - Politicians and policymakers

Our results

- **Deliverables/targets:**
 - Utilisation of tissue samples in research
 - Registry participation
 - Trial participation
 - Access to drugs via MAPs whilst awaiting PBAC approval
 - RVA work on Rare Disease Strategy
 - Preparation notes and info sessions for patient advocates
 - Demonstrable supporter base (ie. membership and supporter numbers)
 - Clear messaging on printed materials, speech notes, online

Our strength

- **Maintain infrastructure to support process:**
 - Fundraising to support research
 - Dedicated liaison officers for clear communication with industry companies
 - Regular communication with FOP families
 - Regular communication with clinicians
 - Ongoing participation of families in organisation
 - Organisational integrity
 - Fundraising to fund lobbying materials (and travel for direct lobbying of decision makers during government review process)



In summary:

OUR KNOWLEDGE

Build community awareness of key topics:

- Understanding of FOP (inc. new insights)
- Clinical trials
- Factors to consider when deciding to enter a trial
- TGA process
- Medicines access programs (MAPs)
- Orphan drug designation
- Principles of effective lobbying
- Upskilling of patient advocates
- PBAC process (including appeal)

OUR RELATIONSHIPS

Build relationships:

- International FOP Association
- Clinicians
- Pharmaceutical and biotechnology companies
- Researchers
- Rare Voices Australia (RVA)
- Politicians and policymakers

FOP Australia's Advocacy Strategy

Our FOP community's steps towards accessing effective treatment for Fibrodysplasia Ossificans Progressiva in Australia and New Zealand

OUR RESULTS

Deliverables/targets:

- Registry participation
- Utilisation of tissue samples in research
- Trial participation
- Access to drugs via MAPs whilst awaiting PBAC approval
- RVA work on Rare Disease Strategy
- Preparation notes and info sessions for patient advocates
- Demonstrable supporter base (ie. membership and supporter numbers)
- Clear messaging on printed and online materials (inc. advocate preparation notes)

OUR STRENGTH

Maintain organisational infrastructure to support process

- Fundraising to support research
- Dedicated liaison officers for clear communication with industry companies
- Regular communication with FOP families
- Regular communication with clinicians
- Ongoing participation of families in organisation
- Organisational integrity
- Fundraising to fund lobbying materials and activities

Implementing the strategy:

1. Review during annual strategic planning to set KPIs for each year
2. Include in board orientation package
3. Share with members in annual report
4. Make publicly available on website