

# FOP Australia Advocacy Strategy

# Drug development and approval process:

## Actions required:

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

Orphan drug designation

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

Cohesive community advocacy

Political will for approval

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

## 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