

# Thoracic Alliance for Cancer Trials

Overview and Membership

April 2016



# There is a significant unmet need in lung cancer research

- Lung cancer is both the most common cancer and the greatest cause of cancer death globally
- Outcomes remain poor with 5-year relative survival of only 14% in countries with the best outcomes
- For patients with advanced incurable disease, there have been major recent advances in EGFR and ALK mutated cancer
- Many more targeted therapies as well as immunotherapies are showing impressive results



# A global effort will address key clinical research challenges

- Trials requiring very large numbers of patients  
e.g. Adjuvant trials post-surgery
- Multimodality therapy  
e.g. Stage III NSCLC
- Rare molecular subgroups  
e.g. Adjuvant TKI following surgery for Alk+ NSCLC
- Rare thoracic malignancies  
Thymic tumours, mesothelioma



# History of TACT

- ASCO 2014 in-principle agreement to establish an international cooperative group for thoracic oncology research
- Steering committee formed
- Seed funding secured AU\$122k (US\$90k)
  - Lung Foundation Australia, ALTG, industry
- Development Officer recruited
- Dialogue with multi-national cooperative groups to evaluate different models
  - Gynaecological Cancer Intergroup (GCIG)
  - Breast International Group (BIG)
- TACT formally established with Board and Membership Working Group September 2015 at WCLC



# The TACT mission

- An international non-profit umbrella organisation for academic research groups from around the world, dedicated to facilitating thoracic oncology research
  - Established 6 September 2015
  - Legal entity: Lung Foundation Australia
  - Secretariat: Brisbane, QLD Australia



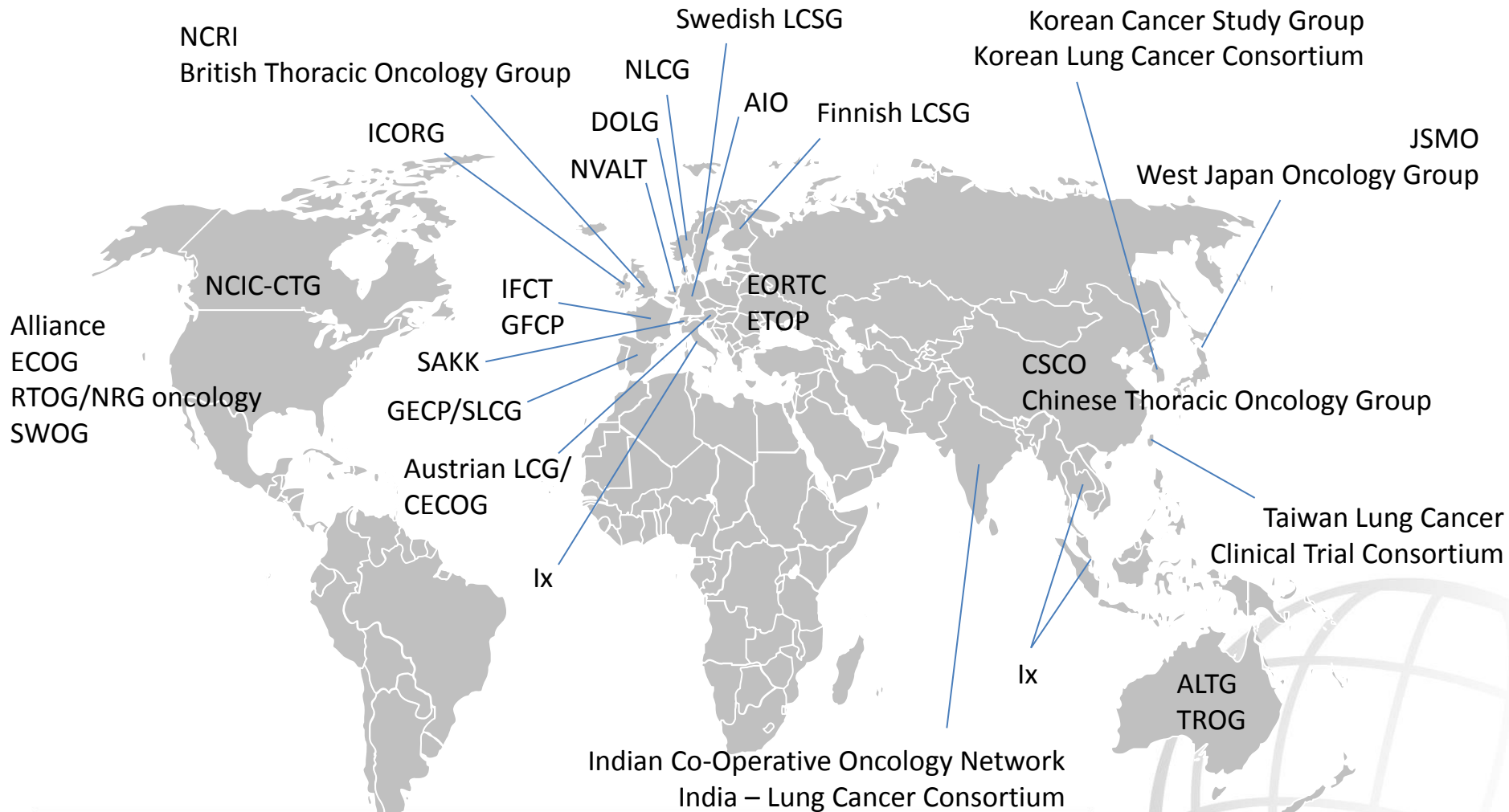
# Board membership illustrates TACT's global network

Paul Mitchell (Chair)	ALTG	Australia/NZ
Glen Goss	NCIC-CTG	Canada
Rebecca Heist	Alliance	USA
Karen Kelly	SWOG	USA
Bartomeu Massuti	GECP/SLCG	Spain
Tony Mok	Asia/IASLC	Hong Kong
Marianne Nicolson	NCRI-CSG	UK
Mary O'Brien	EORTC	Europe
Ken O'Byrne	ALTG/ETOP	Australia/NZ & Europe
Nick Pavlakis	ALTG	Australia/NZ
Suresh Ramalingam	ECOG	USA
Rolf Stahel	ETOP/SAKK	Europe/Switzerland
Virginie Westeel*	IFCT	France
Gerard Zalcman**	IFCT	France

# Board membership illustrates TACT's global network



# More than 25 groups involved to date





# Aims

- Facilitate and promote international research collaboration in thoracic cancer
- Provide a platform to conduct clinical trials requiring multiple groups
- Combine resources and expertise to conduct research more efficiently and reduce duplication of effort
- Allow trials to recruit more quickly
- Establish clinical and translational research priorities

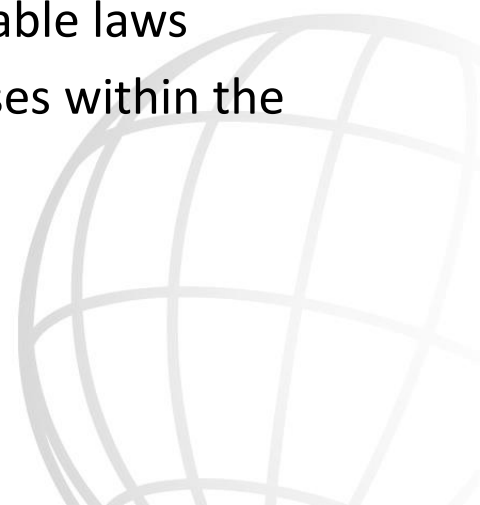


# Activities

- Develop and conduct trials which require large numbers of patients and/or where accrual is difficult
  - Including multi-modality therapy and rare thoracic malignancies or subtypes
- Conduct translational research
- Collaborate with other scientific networks
- Develop models of collaboration with the pharmaceutical and biotechnology industry that preserve scientific independence
- Promote other academic thoracic oncology activities

# Operating principles

- Mutual respect and equity for individuals, cultures and nations
- A strong sense of common purpose
- Providing new opportunities for all members; not replicating an existing group
- Facilitating, supporting and serving as a mechanism to advance the intellectual contributions of individuals and member groups
- Independence from the pharmaceutical/ biotechnology industry, even if trials are industry-sponsored
- Adherence to Good Clinical Practice guidelines and applicable laws
- An agreed set of rules to support fair and efficient processes within the group



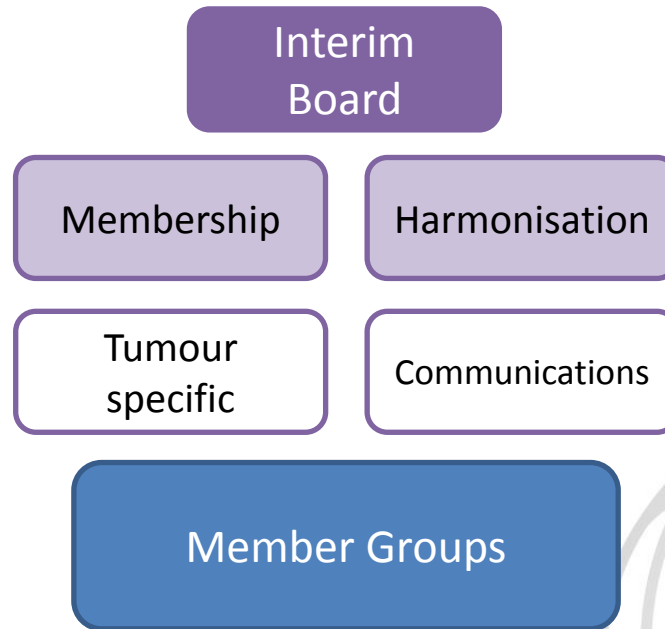
# Board priorities

- Establish the structure
- Demonstrate capabilities
- Develop documentation to support governance and operations
- Build awareness and establish relationships



# Structure 2015-2018

- Steering committee transitioned to Board
- Membership Working Group established
- Other Working Groups to follow



# Full structure in place 2018 (est.)

Board

## Standing Committees

Board Executive  
& Finance

Nominations

Membership

NSCLC  
early

NSCLC  
advanced

Small cell, mesothelioma  
& rare tumours

## Working Groups

Molecular profiling &  
translational research

Harmonisation

General Assembly (Member Reps)



# 2015-2018 is a transition phase

- Twice yearly member meetings at ASCO and WCLC
  - 2016      ASCO Chicago (June 3)      WCLC Vienna (Dec 4)
  - 2017      ASCO Chicago      WCLC Yokohama (Oct)
  - 2018      ASCO Chicago      WCLC Toronto (Nov)
- Quarterly Board and Working Group teleconferences
- Move to a fully democratic structure in three years
  - Board members formally voted in by the General Assembly
  - Appointed Standing Committees and Working Groups
  - General Assembly will discuss trial proposals



# Demonstrate capabilities

- Discussions ongoing to identify a first trial suitable for the TACT mechanism



# Documentation to support governance and operations

- Governance – drafts in progress
  - Mission, Aims and Principles
  - Standard Operating Procedures
  - Membership policy
- Trials – supporting documents
  - Intergroup collaboration agreement
  - Publication and authorship policy
  - Indemnity and insurance
  - Quality assurance including safety
  - Data monitoring committee

# Build awareness and establish relationships

- Website in development
  - [www.TACTlung.com](http://www.TACTlung.com)
- Discussions with additional stakeholders
  - National/trans-national groups e.g. ICORG (IRL), Scandinavia, some Asia
  - Government and regulators e.g. NCI
  - Other groups e.g. International Thoracic Oncology Nursing Forum
- Industry Partners Programme launched
  - Commercial organisations with an interest in contributing to or supporting TACT
  - Representation at open meetings



# Membership of TACT

- Two phases
  - Interim arrangements to guide group establishment
    - Overseen by the Membership Working Group and Board
  - Future arrangements to guide growth and establishment of the General Assembly
    - Overseen by the Membership Committee and Board



# Governance

- Membership Working Group 2015-2018
  - Three Board members
    - Marianne Nicolson (Chair)
    - Karen Kelly
    - Bartomeu Massuti
  - Development Officer
    - Rosalind Wilson
- Standing Membership Committee from 2018
  - Past President/s
    - Immediate Past President as Chair
  - One additional member
  - Executive Officer



# Categories of membership

- Full member
  - Groups whose activities are closely aligned with TACT aims
    - National and trans-national cooperative thoracic oncology or oncology groups who conduct clinical trials
  - Not open to individual researchers or hospitals
- Provisional member and observers (non-voting)
  - Oncology research groups not directly involved in running trials
    - Consumers, laboratory-based research groups, regulatory authorities etc
  - Considered on a case by case basis



# Rights and responsibilities

- Member groups have one vote on matters arising at meetings of the General Assembly and may appoint up to six representatives to attend:
  - Three principal representatives
  - One statistician
  - One data manager/operations expert
  - One translational research representative
- Observer groups have no voting rights
  - One representative to attend General Assembly
  - May be invited to take up observer status on a Standing Committee or Working Group



# Membership criteria

1. At least one ongoing, actively enrolling trial in thoracic cancer
2. Ability to conduct trials under GCP conditions
3. Access to a central data centre – in-house or through a provider
4. Access to statistical support – in-house or through a provider
5. Representatives will attend general meetings and actively participate in Standing Committees and/or Working Groups



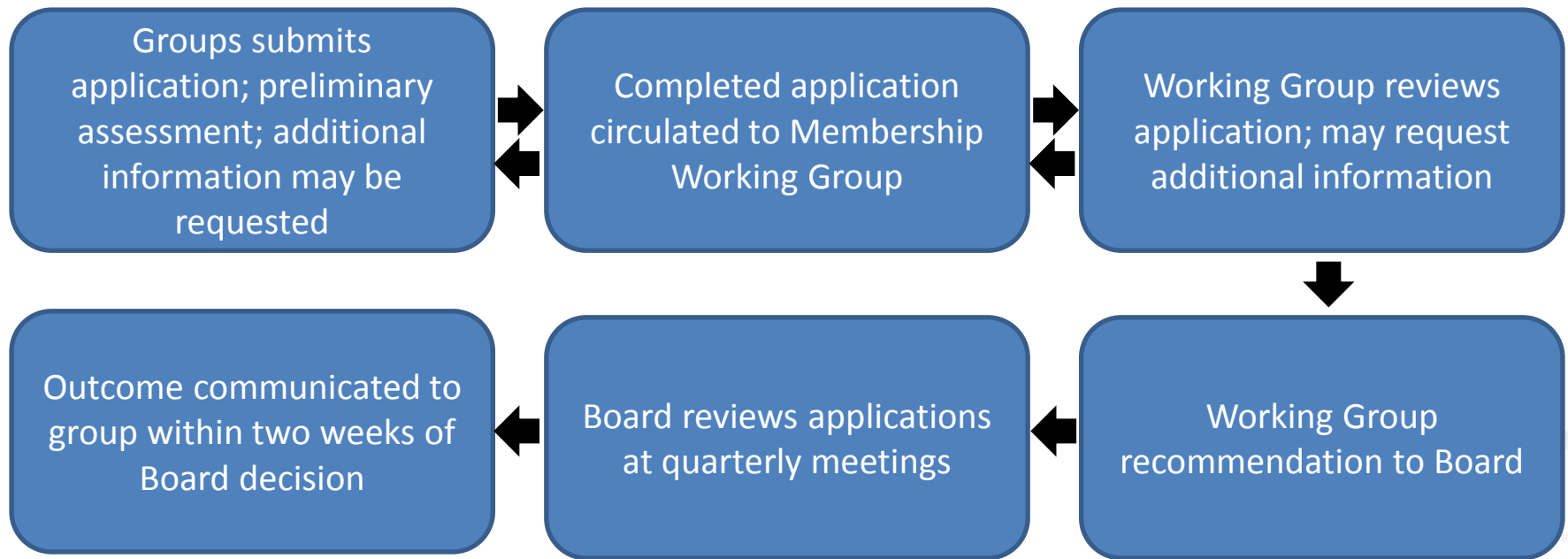
# Dues

- Members of TACT will be invoiced for the amount of AU\$2,000 annually





# Membership application review and approval process



# Summary

- TACT is a unique opportunity to improve the outcomes of patients with thoracic malignancy by facilitating clinical research
- The group intends to learn from and adapt the best elements of other collaborative group efforts to date
  - Truly global membership
  - Key governance and operational elements in place from “go”
  - A genuine collaboration among groups and with external partners

