



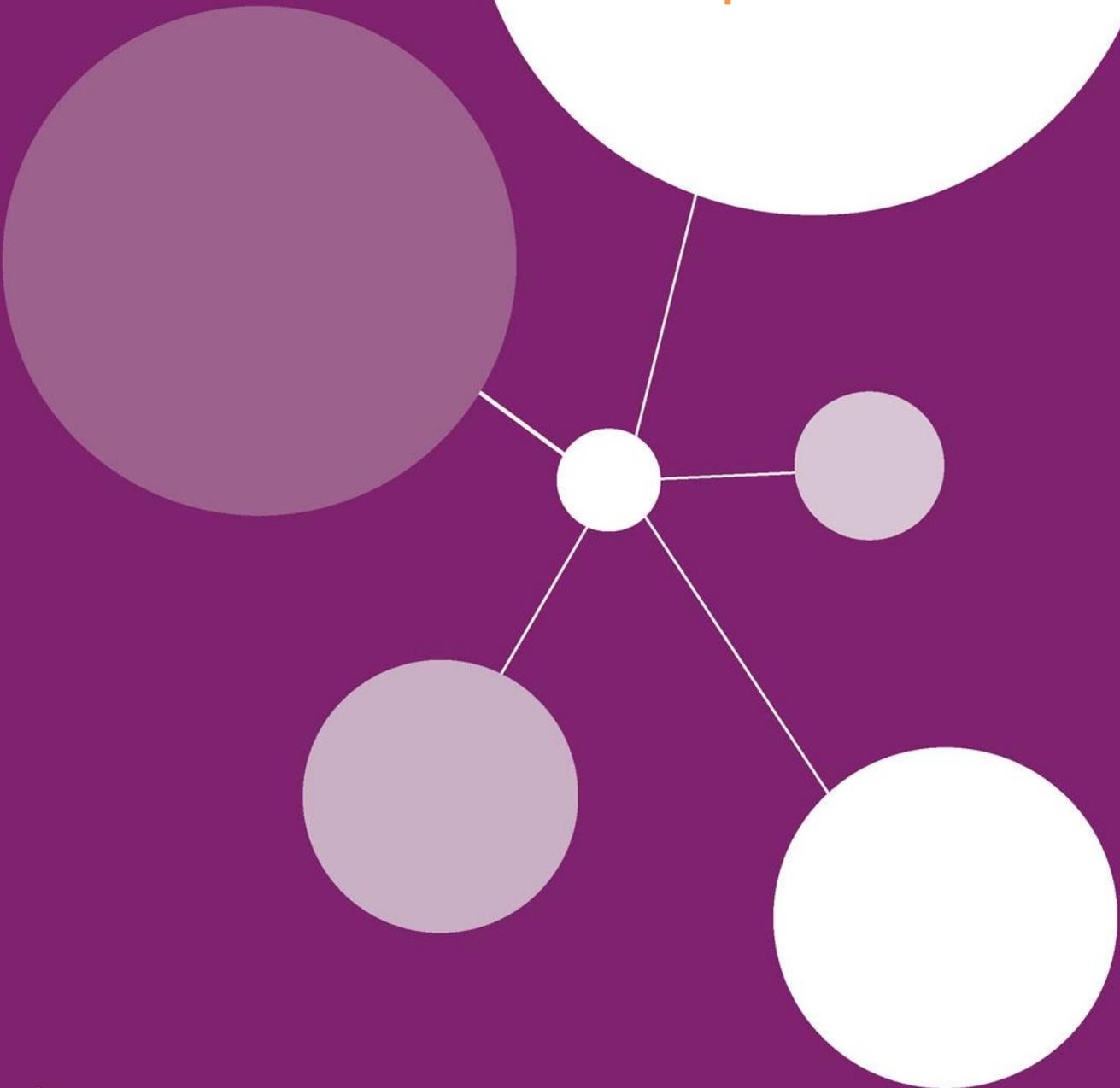
NCRI

National
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**Molecular Biomarkers
Advisory Group**

Annual Report 2015-16



Partners in cancer research

National Cancer Research Institute (NCRI) Molecular Biomarkers Advisory Group

Annual Report 2015-16

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NCRI Molecular Biomarkers Advisory Group Annual Report 2015-16

1. Introduction

In early 2015, the NCRI Biomarkers & Imaging CSG was restructured to create two Advisory Groups: the Molecular Biomarkers Advisory Group (MBAG) and the Imaging Advisory Group. The formation of these two independent Advisory Groups was primarily due to rapid expansion in each area due to new technological developments and improved sensitivities for biomarker detection and enhancements to imaging. It was concluded that it would be more efficient to have two distinct expert groups that could provide pertinent advice on either imaging or molecular biomarkers.

Following a successful national advertisement to recruit to the Advisory Group, the membership was constituted from individuals with expertise in studying a diverse range of cancer biomarkers. The movement towards personalised treatment primarily based on molecular biomarkers emphasises the importance of patient involvement in the activities of the Advisory Group. We have secured excellent consumer representative (Mike Kemp) with expertise in clinical biochemistry. Membership and primary area of expertise of the MBAG is listed below.

Communications within the Advisory Group have been mainly through organised teleconferences or common attendance at specialist meetings/conferences.

2. Membership of the Advisory Group

The Group was identified from the previous NCRI Biomarker and Imaging CSG and other experts in the field of molecular biomarkers.

3. Progress towards delivery of remit

The role of the Advisory Group is outlined to:

1. Provide ad hoc advice on biomarkers in late phase clinical trials to CSGs and others.
Specifically Group members will:
 - Provide advice for trials involving biomarkers.
 - Conduct peer-reviews of the biomarker component of trials.
2. Run an annual educational workshop for the biomarker community.

4. Links to other groups

The Advisory Group has been fully operational since autumn 2015 and is actively promoting its activities to the wider community through various routes:

1. A dedicated page describing the role of the Advisory Group has been placed on the NCRI website which has attracted a small number of enquiries.
2. Following discussions with representatives of the CRUK Clinical Research Committee, the MBAG has agreed to assist in reviewing biomarker applications submitted to the Experimental Medicine Expert Review Panel (EMERP).
3. The MBAG has been highlighted to the Breast Cancer Now charity who have recently updated their application forms to make reference to the NCRI Molecular Biomarkers and Imaging Advisory Groups and to encourage their applicants to directly contact the Advisory Groups. We will explore opportunities to make other cancer charities aware of the NCRI Advisory Groups.
4. The Advisory Group Chair presented at the NCRI CSG Chairs' Forum to promote our biomarker expertise to all CSGs. This has resulted in some initial enquiries on how CSGs can best link to the Advisory Group to consult on biomarker selection for inclusion in

clinical trials. However, we recognise that engagement between the Advisory Group and individual CSGs needs to be strengthened and have proposed a plan to better integrate MBAG and CSGs. Few CSGs have a recognised biomarker expert in their membership and there is a lack of biomarker experts that are members of a CSG and the MBAG. Although it is not practical for MBAG members to attend individual CSG meetings or their subgroup meetings, we feel it is possible to strengthen our links to the CSGs by nominating each MBAG member to establish a link with two CSGs. It would be expected that nominated MBAG individuals would regularly communicate with CSG Subgroup Chairs and report back to the Advisory Group.

5. The MBAG is making efforts to integrate with other experts in molecular biomarkers relevant to cancer and is establishing links with the ECMC Network through the Insight Project Manager (Ilaria Mirabile). This has led to an invitation for the MBAG Chair to attend the ECMC 2016 annual meeting and the ECMC-organised miRNA Workshop in Leeds (July 2016). A further link has been formed with the NCRI Cellular Molecular Pathology Initiative (CM-Path) through Professor Gareth Thomas (Workstream 3: Discovery) where we already have three experts in common to CM-Path and MBAG.

5. Additional outcomes of the Advisory Group

The Advisory Group currently has no further outcomes to report at this time which are not covered elsewhere in the report.

6. Future plans for the Advisory Group

Our aims for the next reporting year are to streamline our shared activities to advice on biomarker components in trials and to conduct a joint educational workshop.

Appendix 1

Membership of the Molecular Biomarkers Advisory Group

Name	Specialism	Location
Dr Michael Kemp	Consumer	Westerham
Professor Thomas Powles	Medical Oncologist	London
Dr Hector Keun	Metabolomics	London
Professor Valerie Speirs	Pathologist	Leeds
Professor Gareth Thomas	Pathologist	Southampton
Professor Craig Robson (Chair)	Professor of Molecular Urology	Newcastle
Professor Jacqui Shaw	Professor of Translational Cancer Genetics	Leicester
Dr Eithne Costello-Goldring	Reader in Molecular & Clinical Cancer Medicine	Liverpool
Dr Aled Clayton	Senior Lecturer in Cell and Molecular Biology	Cardiff
Professor Roz Banks	Translational Scientist	Leeds
Dr Maggie Cheang	Translational Scientist	London

Appendix 2

Group remit

Following the restructure of the Biomarkers & Imaging Clinical Studies Groups (CSG) two new advisory groups were formed:

- Molecular Biomarkers Advisory Group
- Imaging Advisory Group

This paper outlines the role of the Advisory Groups, how it will function and expectations of the Group members.

Role of the Advisory Groups

The role of the Advisory Group will be to:

- Provide *ad hoc* advice on biomarkers/imaging in late phase clinical trials to CSGs and others. Specifically, members of the advisory group will provide advice for trials involving biomarkers/imaging and conduct peer-reviews of the biomarker/imaging component of trials
- Run an annual educational workshop (max capacity: 80 pax) for the biomarker/imaging community

Advice on Trials/Peer review

Trialists will be required to complete a trials registration form, which will be available on the NCRI website. The NCRI CSGs Administrator will forward the completed form to the Chair, who will essentially act as a “filter” and send the trial query to a relevant member of the Advisory Group. The NCRI restricts advisory group members to 10, but to enable the advisory group to function effectively, the Chair may hold an extended list of experts and redirect queries as necessary.

Format of the workshop

The format and content of the workshop will be planned and decided by advisory group members, and they may wish to include a short closed meeting for the advisory group.

What is expected of advisory group members?

Chair

- Maintain general oversight of the group’s advisory activities, redirecting any queries where necessary
- Take minutes and record attendance at teleconferences and annual closed meeting and send to NCRI CSG Administrator
- Provide specialist advice to trialists when requested either directly or through advisory group members
- Prepare and submit annual report
- Plan annual workshop structure and provide details of speakers/extra guests to the Research Project Officer

Members

- Provide specialist advice to trialists when requested
- Assist chair in preparation of annual report
- Assist chair in planning annual workshop format, suggesting topics/speakers/extra guests as necessary.

Members will be asked to step down from the advisory group if:

- They do not provide timely advice to trialists when requested
- They are unavailable for three consecutive meetings (teleconference or annual meeting)

How will success of the advisory group be measured?

A CSG is evaluated yearly using the annual reporting procedure, with more thorough quinquennial review. The advisory group will be required to report on activities in these same timescales, although a more relevant set of metrics as a marker of success will be developed. The metrics for success will be based around:

- The number of trialists seeking and gaining advice from the advisory group
- Involvement of biomarker experts in the trials going forwards – was a one-off piece of advice given or has the involvement been longer-term?
- Others to be agreed following discussion with the advisory groups

Membership rotation and appointment of Members

Rotation

Members are appointed in their own right for three years in the first instance and for a further two years if re-appointed. If all members of a Group are appointed at the same time the Chair should determine in discussion with Group members and the Head of the Clinical Studies Groups, the phasing of membership to ensure continuity within the Group.

Adverts for rotating and new members are placed on the NCRI and NIHR websites, in the winter and summer of each year and circulated to all networks. In addition adverts may be placed in other journals, newspapers and websites subject to the agreement of the Head of the Clinical Studies Groups and availability of funds.

Members due to rotate receive a letter from the Secretariat prior to the advert being placed. Group members receive details of who is due to rotate and when, as part of their meeting papers. Current members due to rotate who have neither submitted an application nor indicated their intention to reapply/not reapply are followed up by the Secretariat.

Appointment

A panel consisting of the following will review applications and appoint accordingly:

- NCRI Clinical Director or nominated Associate Director or ex-Member of NCRI CSG >3 years or ex-CSG Chair of >5 years (To chair the panel)
- Chair of NCRI Advisory Group
- Head of the NCRI Clinical Studies Groups Secretariat

The selection panel meets via teleconference. Applicants are informed of the outcome in writing and successful applicants invited to the next Advisory Group Teleconference.

Attendance of members

The Secretariat keeps records of attendance of all members. Details of attendance at the last three meetings will be routinely presented as part of each set of meeting papers. Members who have failed to attend three consecutive meetings will have their continued membership considered and be asked to leave the Group. The Secretariat will write to such non-attendees. Members who fail to attend two consecutive meetings may be written to by the Secretariat at the discretion of the Chair.

What role will consumers play in the advisory groups?

The role of consumers will be discussed with the advisory groups once they have been established.