

Roles & Responsibilities for Vice Clinical Lead and Clinical Lead

Primary Responsibilities of VCL and CL:

Provide overall clinical leadership and medical oversight for all clinical and translational - studies and programs conducted by Cancer Trials Ireland and represent the views of the Clinical Executive Committee (CEC) at the Board.

Vice-Clinical Lead

The *Vice-Clinical Lead* assumes the responsibilities of the *Clinical Lead* in relation to Medical Oversight and Benefit-Risk Monitoring of Cancer Trials Ireland studies and other responsibilities when necessary when the Clinical Lead is a study Chief Investigator or during planned absences. The position of *Vice-Clinical Lead* is filled through a nomination process and is rotated every four years. After occupying the position of *Vice-Clinical Lead* for a three-year term he/she becomes the *Clinical Lead*. After a four-year term as *Clinical Lead* he/she returns to the role of *Vice-Clinical Lead* for a further year. The selection process includes review by the Board and the CEC.

Responsibilities

- Chairing the *Scientific Management Group* which is responsible for the approval or adoption of studies into the Cancer Trials Ireland portfolio.
- Facilitating the discussion on new studies considering the scientific value, the available funding and the resource requirement.
- Facilitating the discussion on the choice of the National Lead Investigator on collaborative and industry studies.
- Serves as *Safety Monitoring Committee* member for the review and assessment of the continuing benefit/risk of clinical studies.

Clinical Lead

This position of *Clinical Lead* is rotated every four years and is filled by the previous *Vice-Clinical Lead*. The *Clinical Lead* returns to the role of *Vice-Clinical Lead* for a further year after his/her four-year term.

The *Clinical Lead* is available to the GCO for a minimum of one-half day per week of the total two days allocated to meet with members of the *Operations Team* to discuss clinical portfolios, answer questions and provide additional medical oversight.

Responsibilities:

- Leading the CEC, a sub-committee of the Cancer Trials Ireland Board which is the Clinical Leadership body of the organisation responsible for discussing, agreeing and making recommendations to the Board on important issues related to clinical and operational aspects of cancer care delivery relevant to cancer clinical trial execution, and working with the *CEO* and *Head of Clinical Operations* to action CEC decisions.

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Version 1	Effective Date: 30-JUN-2020	

- Chairing the Medical Oversight Meeting and reviewing and assessing safety signals and information related to the medical oversight and continuing benefit/risk monitoring that arise on an ongoing basis during the conduct of studies, decision-making, and making recommendations regarding actions required.
- Serving as Safety Monitoring Committee member for the review and assessment of the continuing benefit/risk of clinical studies.
- Providing input into Risk Assessment of study protocols in the early planning phase and during the lifetime of the study on request.
- Serving as escalation point for issues in relation to studies, investigator sites, non-responsiveness of investigators, publication policy, and scientific misconduct.
- Authorises study protocols, protocol amendments, and Country Specific Appendices on behalf of Cancer Trials Ireland.
- Assists with response to queries received from regulatory authority/ethics committee, e.g. in relation to reported SUSARs.
- Assisting with responses to recommendations of independent DSMBs on studies.
- Reviews and approves study Statistical Analysis Plans and Statistical Reports.

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