

FROM DISCOVERY TO TRANSLATION:

When entering Translational Research, coming from intradisciplinary exploration to multi-disciplinary validating research, many factors beyond the scientific concept dictate success:

- Creating a product that fits the clinical workflow;
- Convincing the regulators that the product is safe and efficacious;
- Convincing the payor that the product is cost-effective;
- Convincing industry that the product represents value.

Before entering the translational pathway and project execution few elements need to be defined with a clear understanding of the end-product definition allowing reverse planning (Figure 1):

- Target Product Profile;
- Medical need & patients involvement;
- Intellectual Property status & Freedom-to-Operate;
- Early HTA: potential for payer reimbursement and cost benefit analysis;
- Core facilities: GMP scalability/GLP/animal models.

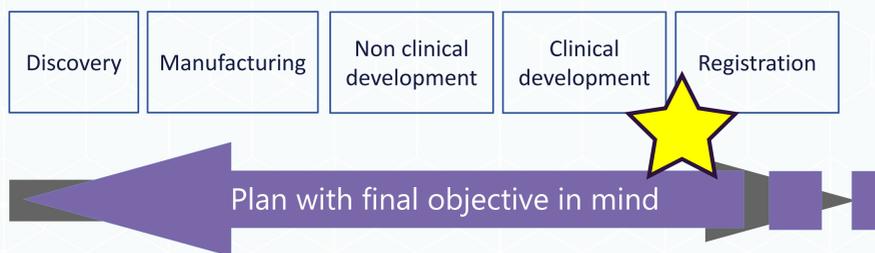


Figure 1: Entering the translational pathway with final objective in mind

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Acknowledgements to the Early Cancer Detection (ECaDE) Steering Committee

EATRIS INSIDE:

EATRIS inside is a service specifically for biomedical research, designed to support the translation of high potential projects through:

- Optimization of their translational strategy on 'non scientific' elements;
- Identification of potential gaps and bottlenecks that may be experienced during project execution;
- Identification of the high-end academic facilities and resources necessary;
- Identify potential gaps and bottlenecks that may be experienced during project execution.



Figure 2: EATRIS Inside 2-stage funding calls.

CASE STUDY: EATRIS Inside 2-TREAT and MEMORABEL

EATRIS performed 13 translational assessments for two programmes funded by ZonMW (Dutch funded agency) looking at 4 components:

- Medical need and end-product focus;
- Translational feasibility;
- Preliminary analysis of regulatory pathway;
- Preliminary analysis of the intellectual property status.

Results: Each project assessment took between 25 and 50 hours depending on the advancement of the project and the complexity of the product to be developed.

The project maturity varied from discovery to clinical stage development. The assessment was perceived the most beneficial when a product or a clinical application was already identified (2-TREAT programme). Less impact of the assessment was perceived for discovery projects (MEMORABEL). Overall EATRIS Inside was perceived as adding value more specifically for the end-product and regulatory pathway definition (Figure 3).



Figure 3: Overview feedback from 2 TREAT and MEMORABEL applicants
2-TREAT: 5 out of 6 applicants answered the survey MEMORABEL: 6 out 7 applicants answered the survey

CASE STUDY:

EATRIS Inside Early Cancer Detection

During the summer of 2017, EATRIS through the ECaDE initiative (Early Cancer Detection Europe) offered its optimization service to the applicants of the TRANSCAN2 JTC 2016 call focusing on validation of early cancer detection marker(s). The assessment focused on:

- Medical need & public health (Clinical expertise & Epidemiology);
- Technology (Assay development);
- Methodology – (Study design & Statistical expertise);
- Infrastructures and resources (Biobanking & pre-analytics).

Results: 4 projects were assessed thanks to the ECaDE Steering Committee. Also very early stage, the assessments were very well perceived by the applicants with very positive feedback (early feedback received by email). Epidemiology, statistical methodology and power analysis, together samples pre-analytics were the fields requesting the most input.

CONCLUSION

- A multidisciplinary expertise is required to perform a comprehensive assessment with a cross-trained team due to the broad range of translational projects which can be expected (products, diseases, stage of development);
- Different added value is perceived based on the stage of the development of the projects:
 - Medical discovery: Awareness and exposure of PI to Translational Research and the development path ahead;
 - Translational phase (product identified): Technical input on project feasibility, development path and market (medical need) opportunity.
- End Product" definition is perceived as the highest value for all programs (regardless of stage of development).