College of the European School of Oncology

Learning to care online

e-session 531001

Writing a grant

Expert: **Dr Alessandra Gennari**, Head, Division of Oncology, Maggiore della Carità Hospital, Novara, Italy

Discussant: **Dr Luca Bertolaccini**, Thoracic Surgeon, European Institute of Oncology, Milan, Italy

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WRITING A GRANT

Alessandra Gennari, MD PhD
Department of Traslational Medicine
University of Eastern Piedmont
Head, Division of Oncology
Novara, Italy

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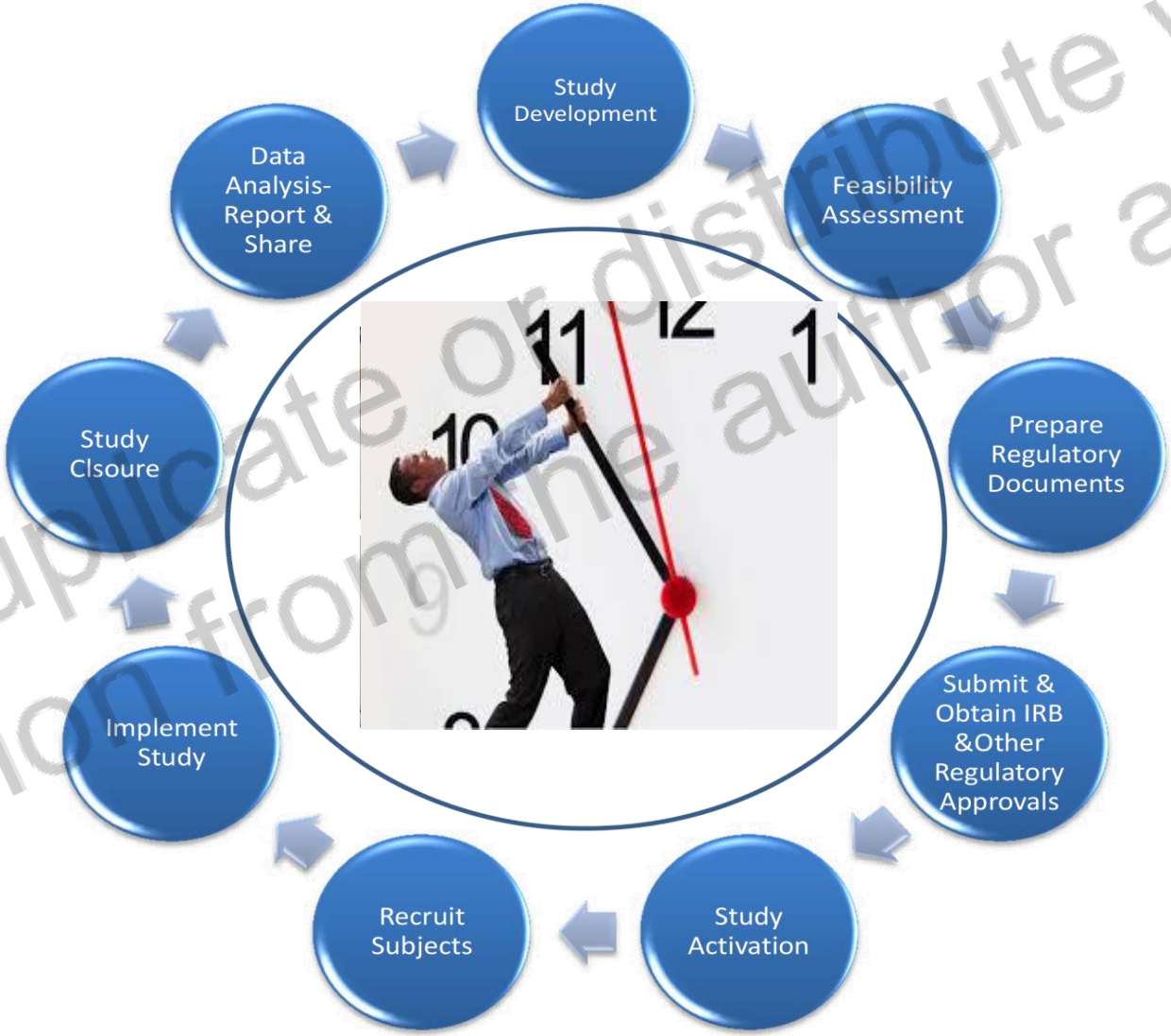
Life Cycle of a Research Project



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Project Development

SCIENTIFIC HYPOTHESIS
The idea

PROPOSAL DEVELOPMENT

PROJECT IMPLEMENTATION

RESEARCH PARTNERS AND CONSORTIUM

FEASIBILITY AND IMPACT ON CLINICAL PRACTICE AND FUTURE RESEARCH

FEASIBILITY : ADMINISTRATIVE ISSUES REGULATORY ISSUES

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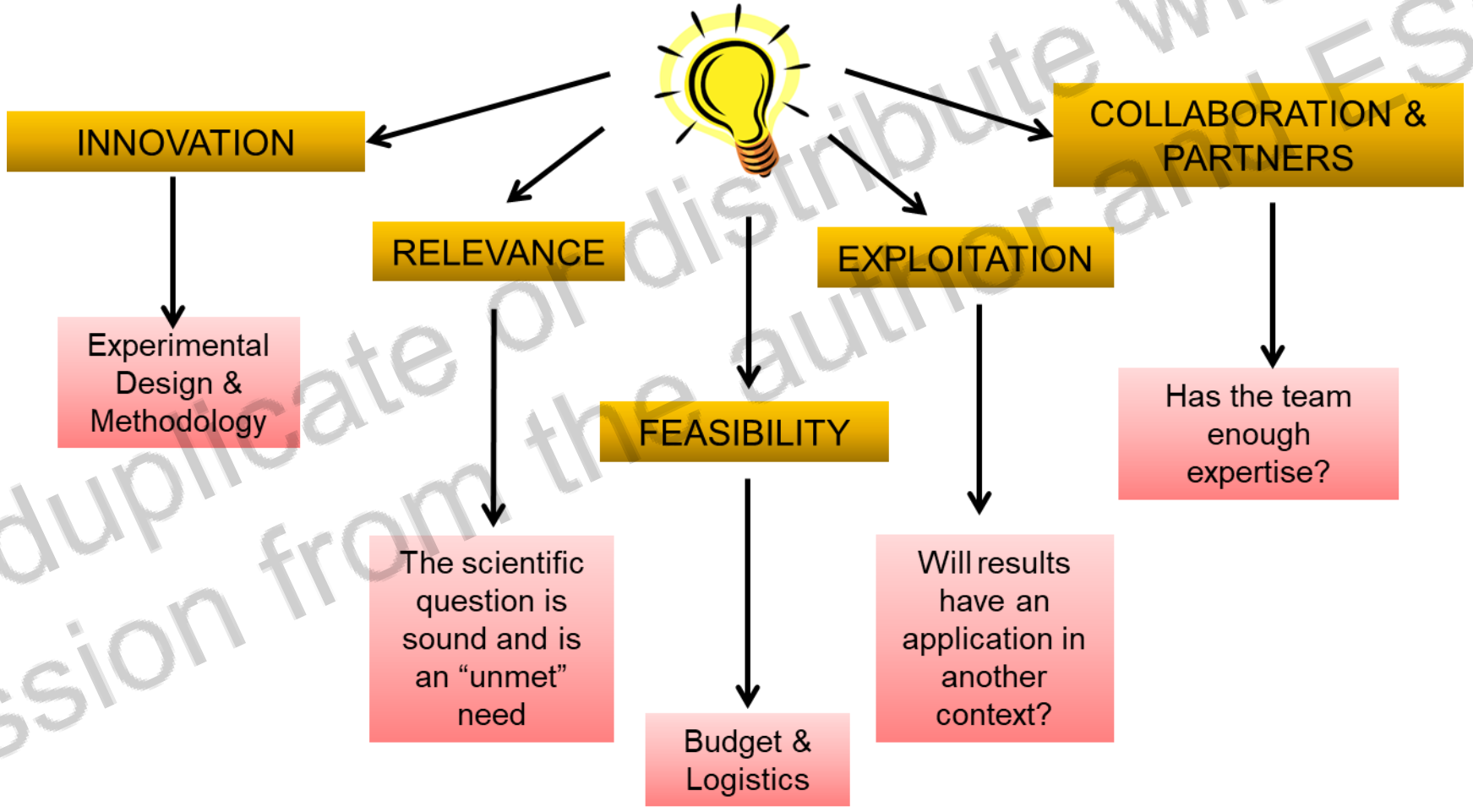
STEP 1: from THE Idea to the Project



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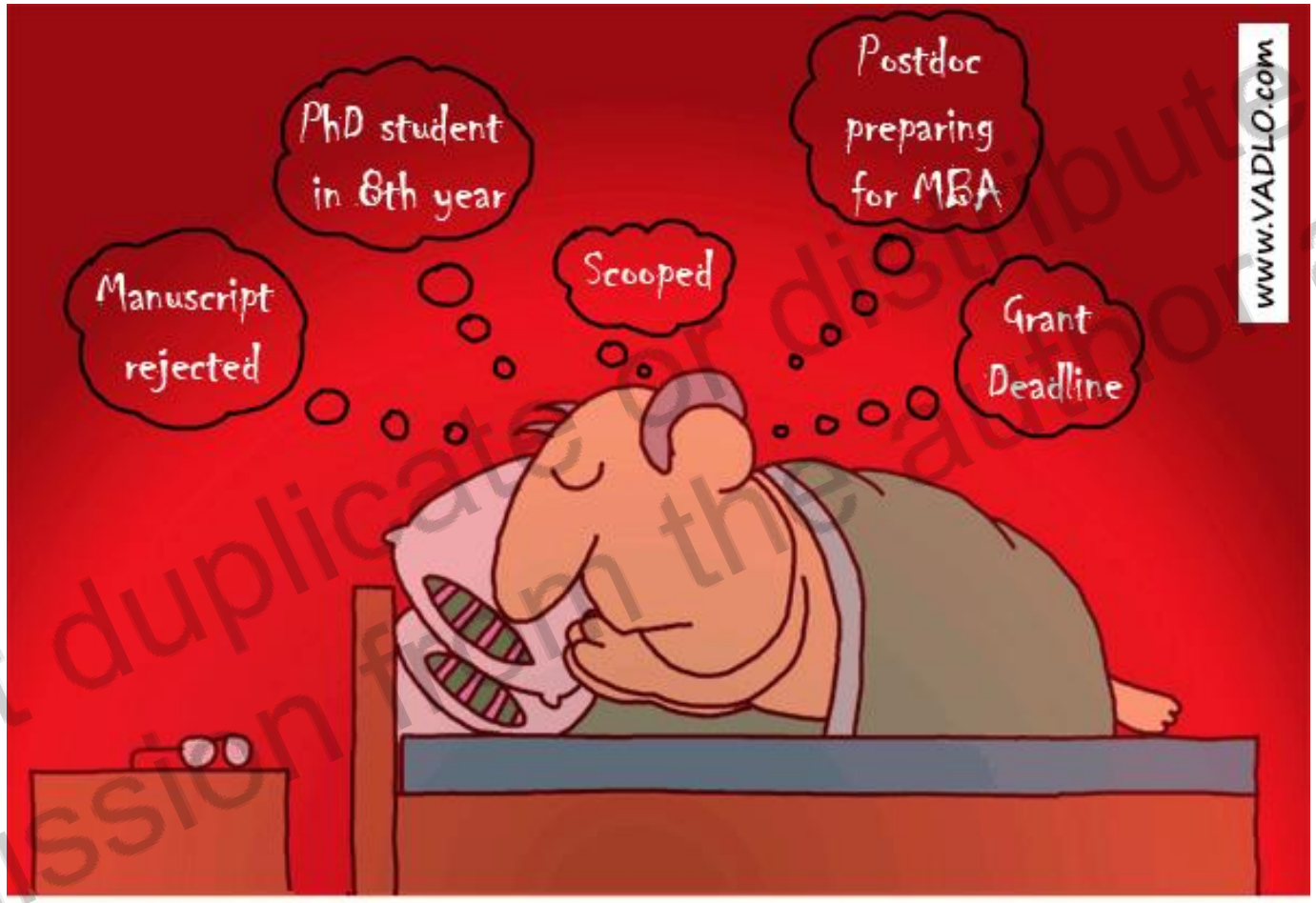
STEP 2: Key People

- You, the PI
- Your Scientific Partners
- The Network
- The «Statistician»
- Your Local Support Team

The PI



It ain't so easy being a PI.

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How are you going to be evaluated?

The person

- Academic achievements
- Creativity, scholarship
- Demonstrated passion/commitment, or genuine, new-found interest in exploring a career path
- Ability to express oneself
- Depth

- Consult colleagues. Don't be afraid to discuss your proposal with colleagues, or even with the grants officer at the funding body. Early discussions can ensure that your proposal is targeted appropriately.

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The Partner Consortium

SCIENTIFIC HYPOTHESIS
The idea

PROPOSAL
DEVELOPMENT

PROJECT
IMPLEMENTATION

RESEARCH PARTNERS
AND
CONSORTIUM

FEASIBILITY AND IMPACT
ON CLINICAL PRACTICE
AND FUTURE RESEARCH

FEASIBILITY :
ADMINISTRATIVE ISSUES
REGULATORY ISSUES

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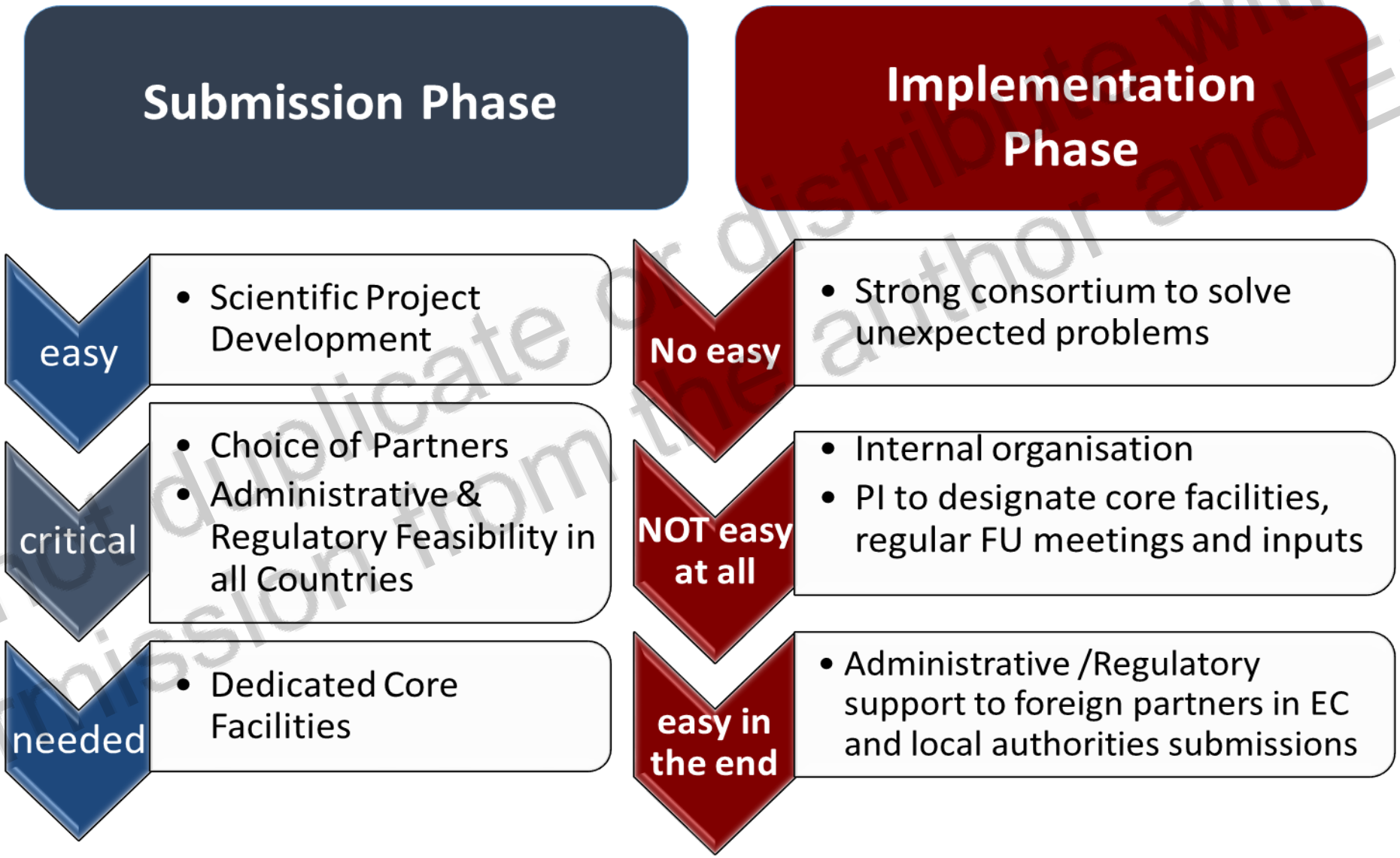

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TRANSCAN

The ET-FES Consortium

1. **Partner # 1:** Project Coordinator *Alessandra Gennari,* Genova, IT
2. **Partner # 2:** Dino Amadori, Meldola, FC, IT
3. **Partner # 3:** Javier Cortes, Barcelona, E
4. **Partner # 4:** Nadia Harbeck, Munich, DE
5. **Partner # 5:** Etienne Brain, St Cloud, FR

KEY ISSUE

Deadline October 31, 2019

Project Presentation
OVERALL SUMMARY
HYPHOTHESIS AND SPECIFIC AIMS
METHODOLOGIES AND STATISTICAL ANALYSIS
SIGNIFICANCE AND INNOVATION
SINERGY OF RESEARCH TEAM
BIBLIOGRAPHY
DELIVERIES AND MILESTONES
FACILITIES
RILEVANCE SSN

Budget Presentation	€
STAFF/RESEARCH CONTRACTS	
EQUIPMENT (leasing)	
SUPPLIES	
SUB-CONTRACTS	
MODEL COSTS	
IT SERVICE	
PUBLICATION COSTS	
MEETINGS	
TRAVELS	
OVERHEAD	
TOTAL	

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Building a Network

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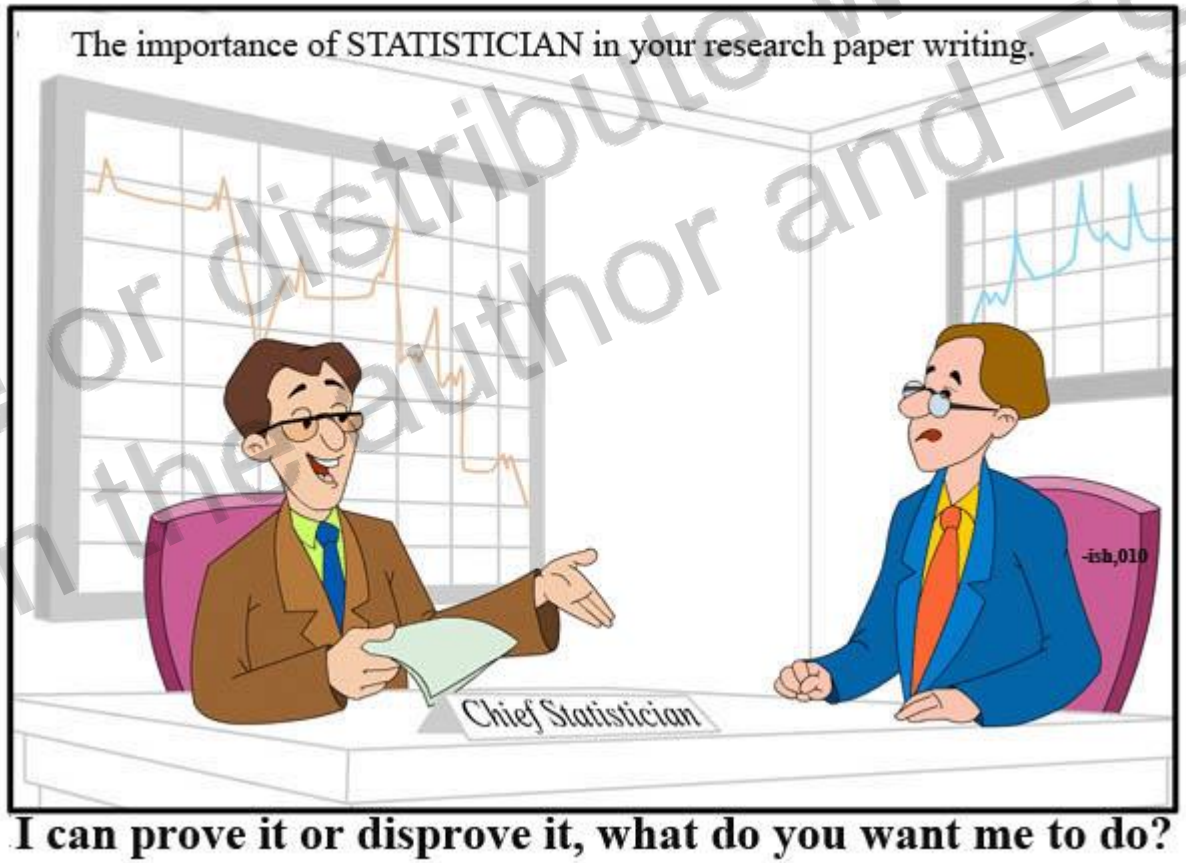
The Study Design and Flowchart

- Title
- Abstract (or Research Plan Summary)
- Research Proposal:
  - Research Question
  - Background
  - Study Design and Methods
- References



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Before starting……

- ALWAYS read carefully the call for proposal in its entirety, before you begin writing
- Follow instructions!!!!
- Keep it simple to understand
- Do not do or add anything they do not ask!!!

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The Title

- Title
- Abstract (or Research Plan Summary)
- Research Proposal:
  - Research Question
  - Background
  - Study Design and Methods
- References

- Title: This is the first impression the reader gets. The title should be short and clear, and the reviewer should be able to understand from the title the intentions of the research. A catchy title posing a question or including an apparant contradiction or acronym may be more easily remembered by a reviewer.

MINDACT

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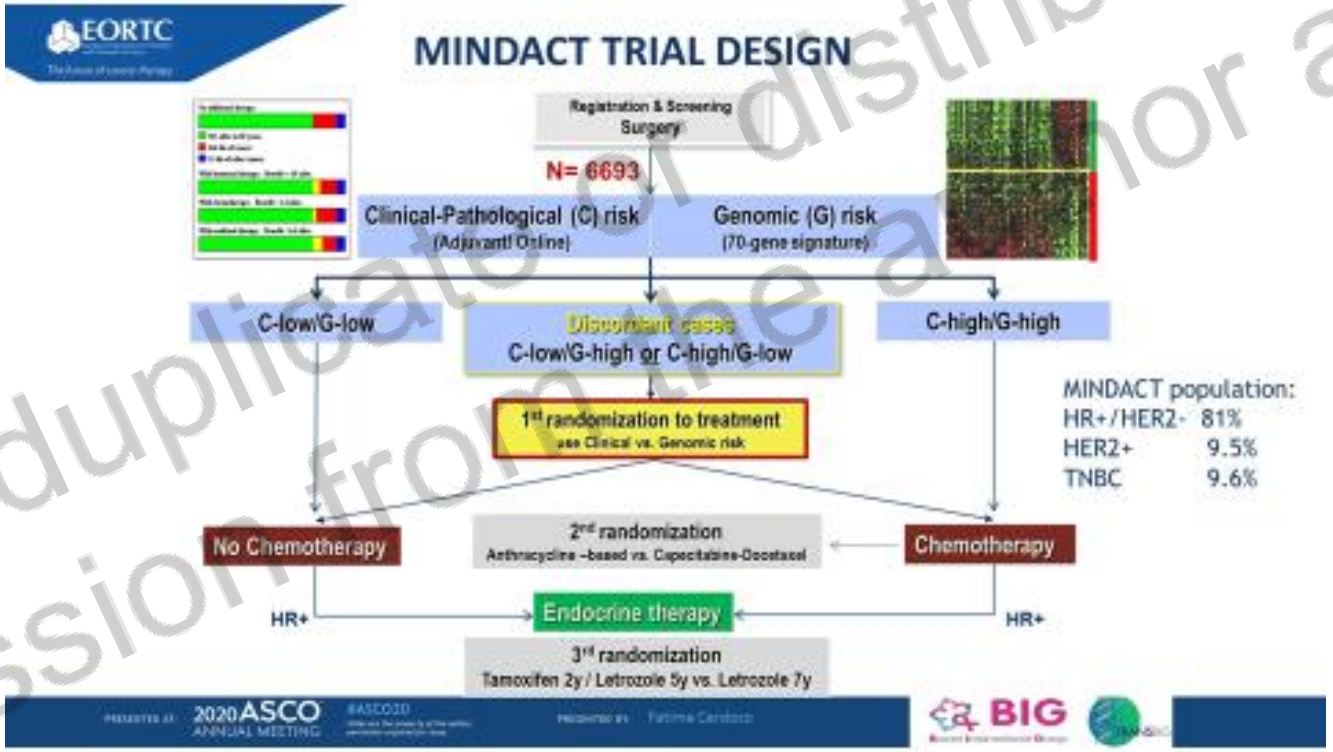
Oral presentation #ASCO20

MINDACT: Long-term results of the large prospective trial testing the



Presented By Fatima Cardoso at ASCO 2020

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Study Design and Structure

Aim n° :		Participant(s) responsible for the aim/workload
1	To compare disease control rate (DCR) in ER+ MBC patients with 18F-FES SUV < 2 treated with endocrine therapy (standard arm) versus CT (experimental arm) (WP1)	Project Coordinator and all research partners (#1,2,3,4,5)
2	To optimise 18F-FES production (WP2)	Advanced Accelerator Applications, (no budget requested)
3	To evaluate the relationship between gene alterations (mutations and/or gene amplifications) of estradiol receptors ESR1/ESR2 genes and 18F-FES SUV (WP3)	Research partner #2
4	To develop a predictive score of endocrine responsiveness based on 18F-FES SUV (WP4) and clinical and biological Information	Project Coordinator

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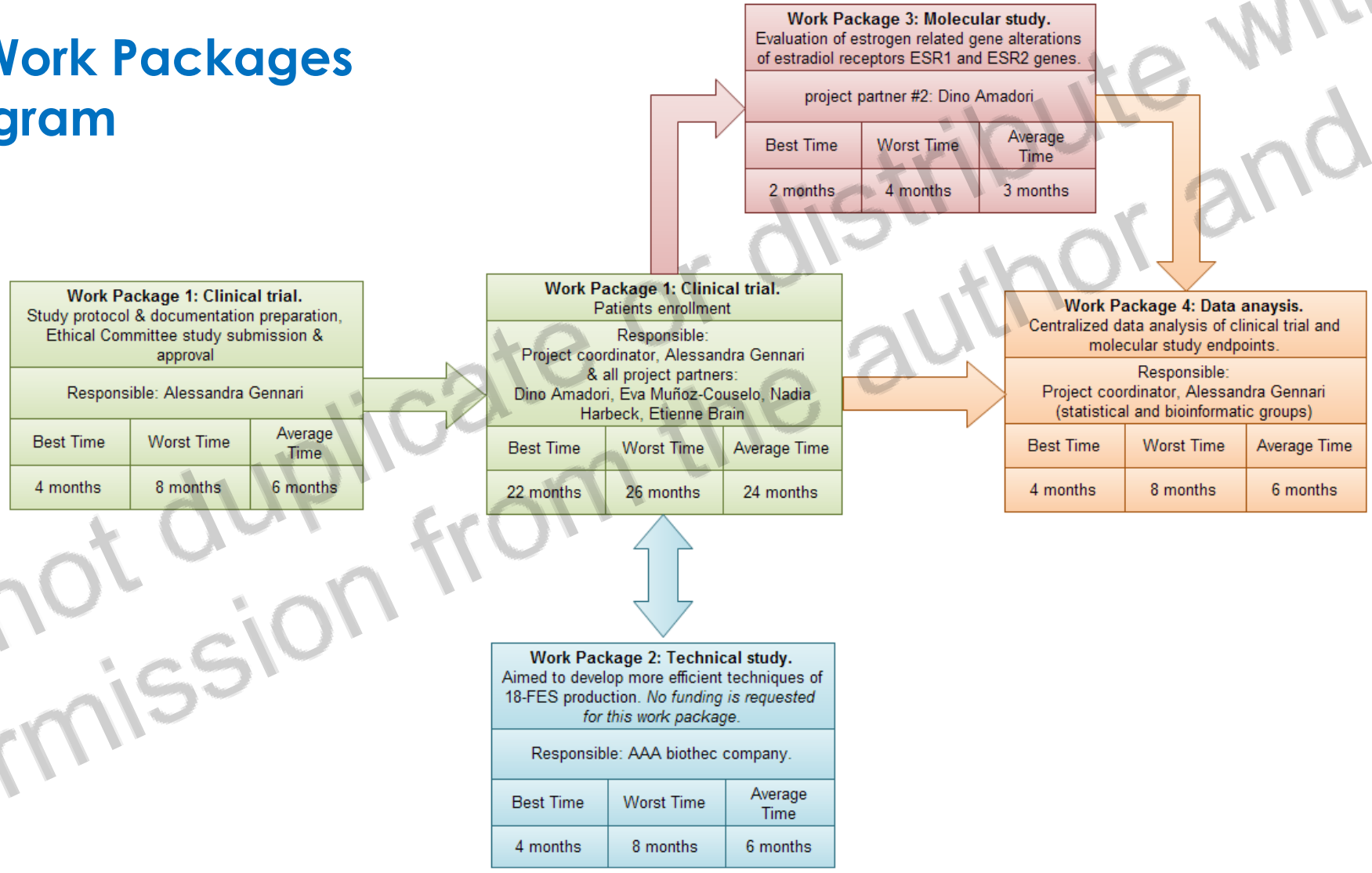
Define the Activities and Roles

ET-FES: Work Packages Pert Diagram



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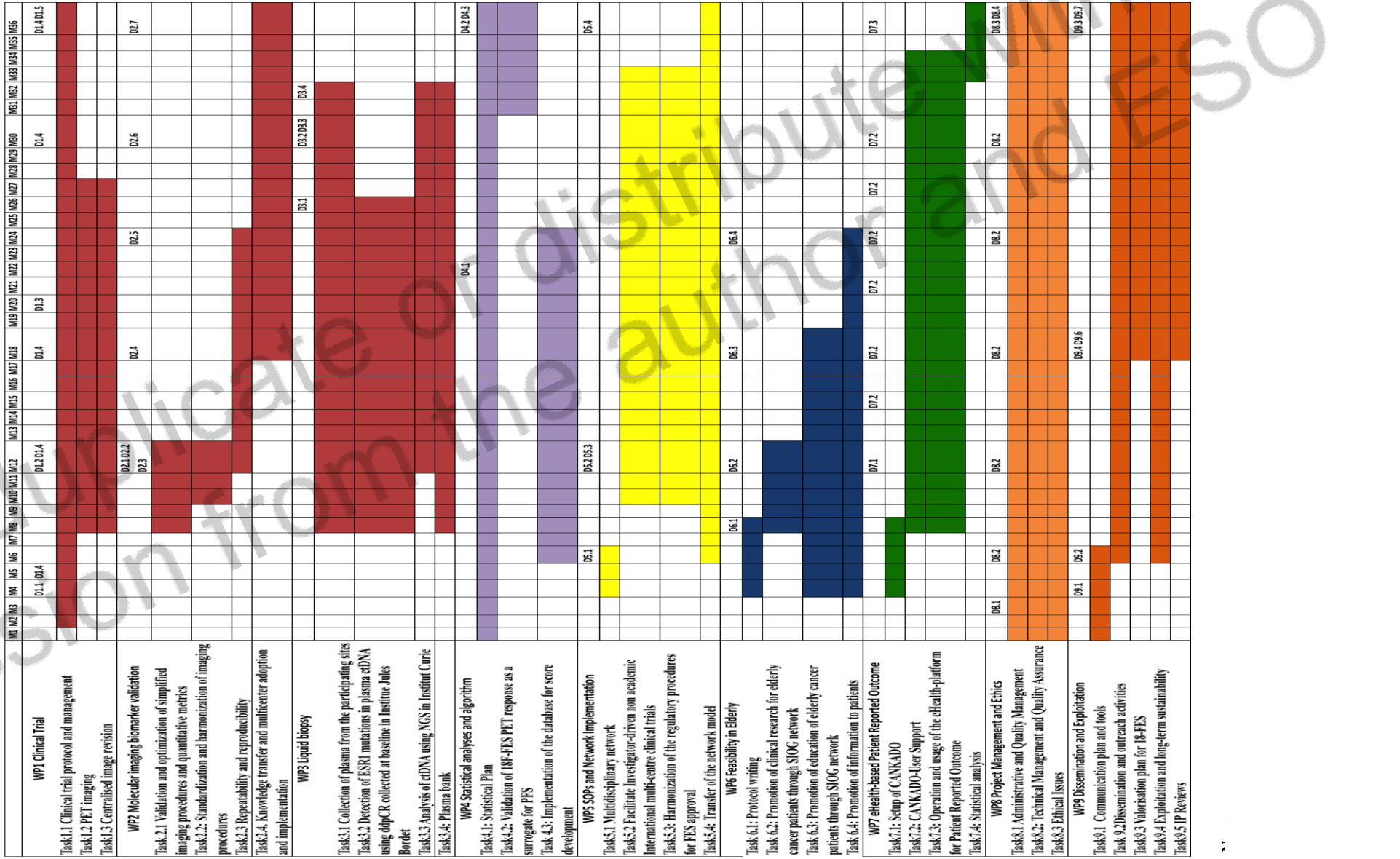
Define the Activities: GANTT Diagram



1. Analysis of the Activities

- Protocol writing
- Implementation of Study Documents (IB, CTA, TMF, Contracts….)
- Preparation of Centre-specific documents (ICF, MMG, IMF, Contracts…)
- EC and CA submission and response to raised issues
- Definition of eCRF and implementation
- Monitoring Plan
- Data Management Plan
- Statistical Plan

2. Analysis of the Activities

- SIV
- Monitoring (remote and on-site) Newletter e Investigator Meeting
- Drug supply and pharmacovigilance
- Data queries
- Data base lock
- Statistical Analyses (Statistical report)
- Publication and dissemination of results

Study Amendments (EC): 2.4/trial

How to define your budget

- Type of study: observational, prospective, retrospective, interventional ….
- Study design, traslational, randomised etc…..
- N patients
- N centres
- Treatment duration
- Follow up duration
- Profit, no profit (2004-?)
- Drug supply: company, sponsor, NHS
- Other procedures
- Data Management
- Biomarkers?

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Other Costs

Budget MODEL	€
STAFF/RESEARCH CONTRACTS	
EQUIPMENT (leasing)	
SUPPLIES	
SUB-CONTRACTS	
MODEL COSTS	
IT SERVICE	
PUBLICATIONS	
CONFERENCES	
TRAVELS	
OVERHEAD	
TOTAL	

Easy to define

- ✓Insurance
- ✓CE Fee
- ✓Fee for Centre Activation
- ✓Fee/pt
- ✓IDMC
- ✓Other services (lab costs, delivery etc)
- ✓Investigator Meeting
- ✓ConveConferences
- ✓Publications, Dissemination (poster etc)
- ✓Overhead

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Other Costs: Project Personnel

Work package No	Work Package Title	Lead Participant No	Lead Participant Short Name	Person-Months	Start Month	End month
WP1	Clinical Trial	2	IJB	192	2	30
WP2	18F-FES PET/CT molecular imaging biomarker validation	3	UMCG	120	8	36
WP3	Liquid biopsy	4	IJB	88	8	32
WP4	Statistical analyses and algorithm	1	EOG	114	8	32
WP5	SOPs and Network Implementation	5	IRST	154	1	36
WP6	Feasibility in the elderly	9	SIOG	75	4	32
WP7	eHealth-based Patient Reported Outcome (ePRO)	8	LUM	112	4	36
WP8	Project Management and Ethics	1	EOG	120	1	36
WP9	Dissemination and Exploitation	7	VHIO	95	1	36
Total months				1070		

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Other Costs: Project Personnel

3 - Budget for the proposal

No	Participant	Country	(A) Direct personnel costs/€	(B) Other direct costs/€	(C) Direct costs of sub-contracting/€	(D) Direct costs of providing financial support to third parties/€	(E) Costs of inkind contributions not used on the beneficiary's premises/€	(F) Indirect Costs / € (=0.25(A+B-E))	(G) Special unit costs covering direct & indirect costs / €	(H) Total estimated eligible costs / € (=A+B+C+D+F+G)	(I) Reimburse-ment rate (%)	(J) Max.EU Contribution / € (=H*I)	(K) Requested EU Contribution/ €
1	Ente Ospedaliero Ospedali	IT	597000	159530	97000	0	0	189132,50	0	1042662,50	100	1042662,50	1042662,50
2	Institut Jules Bordet	BE	534000	342920	43200	0	0	219230,00	0	1139350,00	100	1139350,00	1139350,00
3	Umcg	NL	408000	125532	0	0	0	133383,00	0	666915,00	100	666915,00	666915,00
4	Usmi	IT	183000	31355	0	0	0	53588,75	0	267943,75	100	267943,75	267943,75
5	I.r.s.t Srl	IT	318000	111726	0	0	0	107431,50	0	537157,50	100	537157,50	537157,50
6	Institut Curie	FR	162000	94507	0	0	0	64126,75	0	320633,75	100	320633,75	320633,75
7	Vhio	ES	309000	92784	0	0	0	100446,00	0	502230,00	100	502230,00	502230,00
8	Lmu Muenchen	DE	336000	124320	86000	0	0	115080,00	0	661400,00	100	661400,00	661400,00
9	International Society Of Geriatric	CH	216000	37009	0	0	0	63252,25	0	316261,25	100	316261,25	0,00
10	Advanced Accelerator Applications	FR	78000	513364	0	0	0	147841,00	0	739205,00	100	739205,00	739205,00

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Risk Analysis: What Else?

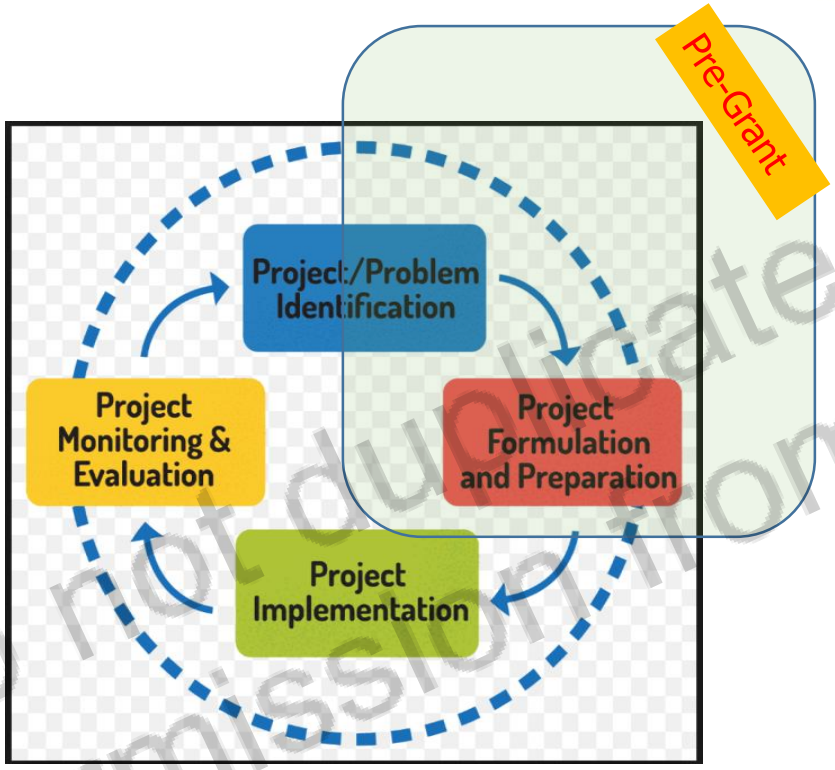
The PI, must take care of:

- Scientific Reports
- Economic Reports
- Division of funding (tranches)
- VAT

Risk Analysis:

- 85% of clinical trials have a delay
- 94% > 1 month
- This must be planned a priori in the GANTT diagram

Project Cycle



NON EC – LINKED Programs

MULTILATERAL FUNDING

The Global Fund to Fight Aids, Tuberculosis and Malaria

UNITAID

Drug-purchasing facility (provides funding grants) Hosted by WHO

NGO & PRIVATE FOUNDATIONS

Clinton Health Access Initiative (CHAI)

Partners In Health

Local NGOs

RTI INTERNATIONAL

The World Bank

UNDP

UNHCR

UNOPS

UNFPA

unicef

ROLL BACK MALARIA

World Health Organisation

Stop TB Partnership

GLOBAL DRUG FACILITY (GDF)
The Global Health Network

MULTILATERAL PROGRAM & FUNDING

JICA

DFID

aetna AstraZeneca Boehringer Ingelheim BRIGHAM AND WOMEN'S HOSPITAL Bristol-Myers Squibb

EMD SERONO Lilly FDA FIBROCELL gsk

IBM INOVA JDRF janssen MAYO CLINIC

MERCK NIH NATIONAL CANCER INSTITUTE NOVARTIS Pfizer PRECISION FOR MEDICINE

REGENERON Roche SANFORD HEALTH Shire Takeda

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Timeline (grants)

January 2nd 2017:
Start of grant

February:
Call for proposals

March:
Deadline for applications

April:
Reviewers assignment

June:
Deadline for review

August:
Analysis of reviews,
initial ranking

September:
evaluation of
final report
of previous funding (IG)

October:
Study section
Meeting (IG, MFAG)

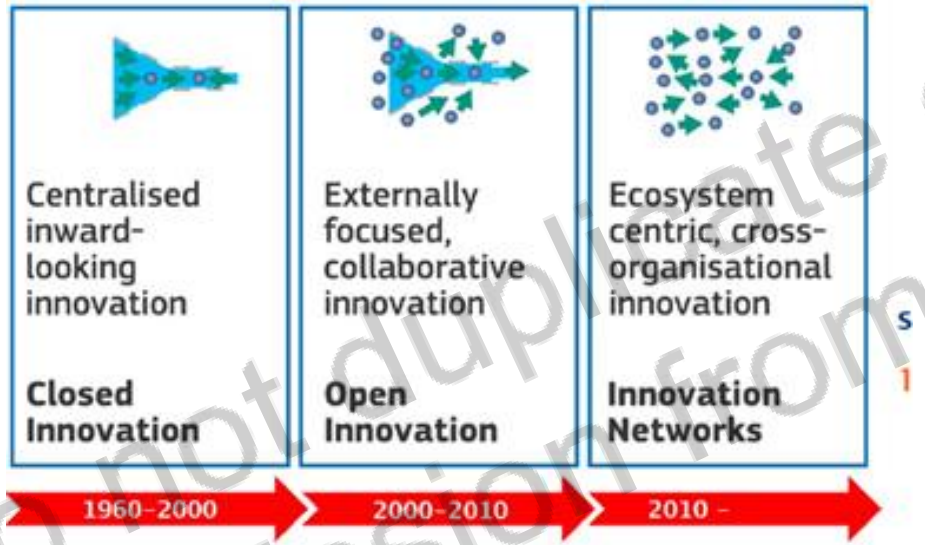
November:
Board of Directors
meeting and
notification of results

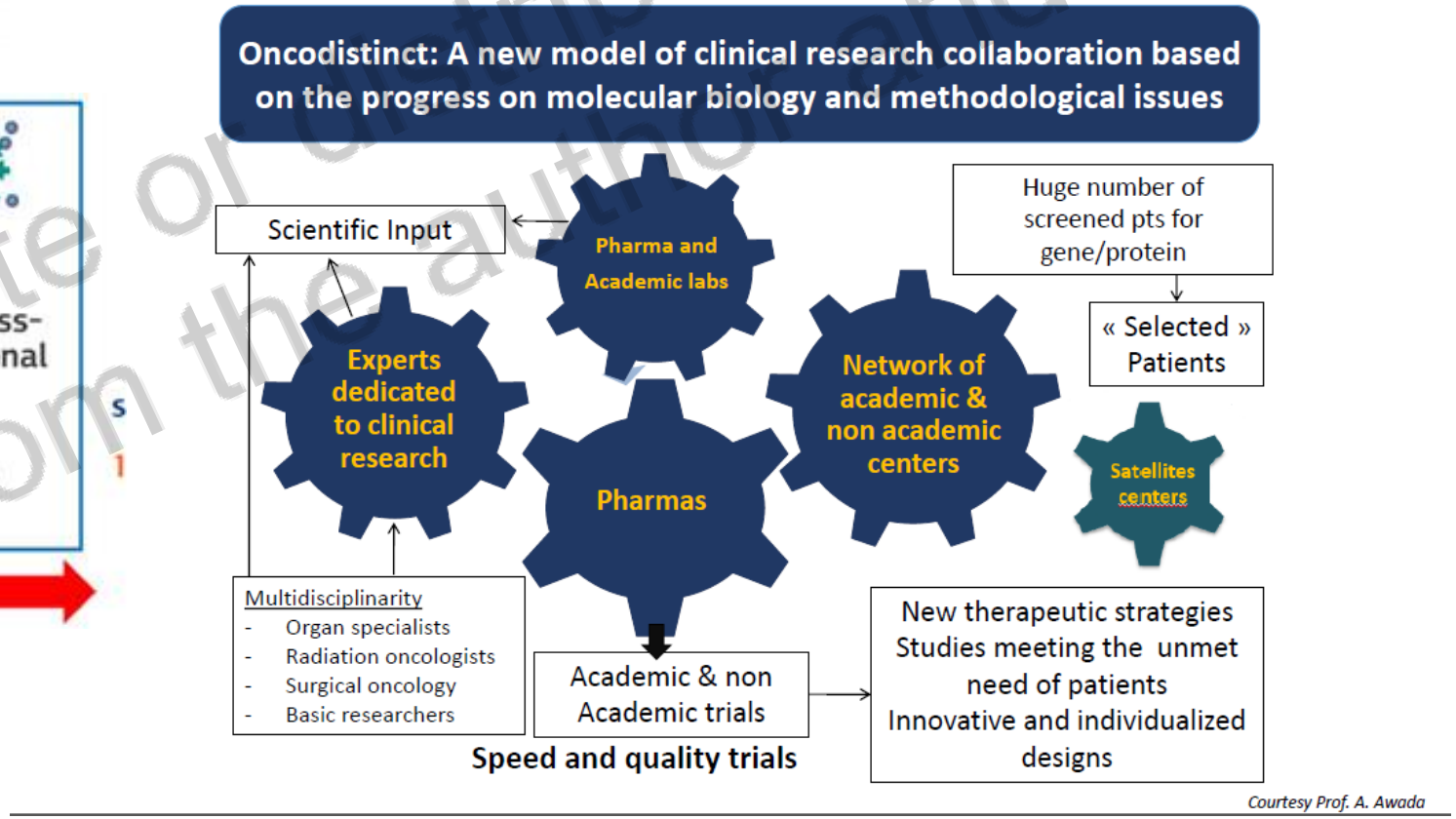
Translational Medicine

REVIEW Open Access

Changing R&D models in research-based pharmaceutical companies

Alexander Schuhmacher[1*], Oliver Gassmann[2] and Markus Hinder[3]





Courtesy Prof. A. Awada

CLINICAL TRIAL CENTER

- Administrative , business, IT support
  (agreement, budget, grant monitoring with dedicated personel)
- Legal competence (insurance, privacy, data ownership, patent)
- Clinical research team (research nurse, study coordinators, data manager, technicians, pharmacists)
- Statistical and methodological support
- Biologist , bioinformatics for translation aspects

Multiprofessional Team for clinical/traslational research

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Thank you!

for participating in this

Dedicated ESCO e-session

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