

APRIC (Associazione Per la Ricerca Clinica)

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General Assembly, 1 June 2016



Background

- APRIC was founded in 2001
- It is a non-profit group promoting academic research in solid tumors, consistently with an Italian law regulating non-profit clinical trials
- Founding members represent Universities, public hospitals and the National Cancer Institute of Naples
- It's focus is not limited to thoracic cancer

Background

- Colorectal cancer
- Gynecologic cancer, then moved into the MITO group
- HCC, evolving from the CLIP group
- Lung cancer, evolving from...

ELVIS

Efficacy of vinorelbine in elderly NSCLC patients.

JNCI 91: 66-72, 1999

MILES-1

Efficacy of a non-platinum doublet in elderly NSCLC patients.

JNCI 95: 362-372, 2003

GEMVIN-3

Efficacy of a non-platinum doublet in adult NSCLC patients.

BR-14

JCO 21: 3025-3034, 2003



Key people (outside my Inst)



Cesare Gridelli
Director Oncology Department
Moscati Hospital, Avellino



Fortunato Ciardiello
Professor of Oncology,
Second University Naples
President ESMO



Ciro Gallo
Professor of Statistics
Second University Naples

Key people (Inside my Inst)



Alessandro Morabito
Director
Medical Thoracic Oncology



Jane C. Bryce
Research nurse
Clinical Trials Unit



Nicola Normanno
Director
Lab Molecular Oncology



Marilina Piccirillo
Oncologist
Clinical Trials Unit



Gaetano Rocco
Director Thoracic Surgery
President ESTS



Gennaro Daniele
Oncologist
Clinical Trials Unit

Trial process

- Trial proposals are discussed within annual group meeting (next July 7)
- The key people I showed before look for funding and support
- Protocol development and conduct of the studies are in charge of the Clinical Trials Unit of the NCI Naples that usually act as sponsor
- Statistical methodology is in charge of the Second University of Naples

Operative structure

- Extensive experience done in cooperation of the MITO group within GCIg and ENGOT intergroup activities
- Trials are coordinated through a web platform allowing
 - Registration/randomisation/eCRFs
 - Data handling/monitoring/eQueries
 - Uploading of imaging (for independent review)
 - Drug request and tracking facilities
 - Specific profiles for researchers, data manager, ethical boards, administrative offices, CRO, pharmacy
- Since 2007: >250.000 web accesses and around 200.000 eCRFS collected

Some phase 3 studies completed

TORCH Erlotinib→chemo vs Chemo→erlotinib in non-selected NSCLC patients
JCO 30: 3002-11, 2012, JTO 7: 1830-44, 2012

CAPPA-2 Efficacy of cisplatin in PS2 NSCLC patients.
Lung Cancer 81: 77-83 , 2013

STAD-1 Efficacy of a toxicity-adapted dosing strategy in 1° line treatment of SCLC
ASCO 2015 (oral), submitted

Some phase 3 studies ongoing

MILES-3 Testing the efficacy of platinum in elderly NSCLC patients (close to the end)

MILES-4 Testing the efficacy of platinum and comparing pemetrexed with gemcitabine in elderly NSCLC patients (close to the end)

BEVERLY Testing the efficacy of bevacizumab added to erlotinib in patients with EGFR-mutated NSCLC (just started)

Intergroup Collaborations - Current

Intensive collaboration with CCTG (ex NCIC-CTG)

BR-26 Efficacy of dacomitinib in pretreated NSCLC patients

Lancet Oncol 15: 1379-88, 2014

BR-31 Testing the efficacy of durvalumab as adjuvant treatment of patients operated for NSCLC (ongoing)

IND-227 Testing the efficacy of pembrolizumab in 1^o line treatment of mesothelioma (starting soon)

Intergroup Collaborations – Issues

- Uncertainty about the effects of incoming EU regulation for clinical trials (end 2018)
- Apparently, collaborative trials should be made easier
- But there is a growing role of the regulatory agencies that will change many of the procedures in Europe...

Thank you
and best wishes to TACT!

