This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098"

REVERT Project

Targeted therapy for advanced colorectal cancer patients

Kick-off meeting

Prospective study to evaluate the association between individual profiles and clinical outcomes in 1st line metastatic colorectal cancer (mCRC) patients

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Full Professor of Medical Oncology

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STANDARD STRATEGY

1ST LINE THERAPY FOR STAGE IV CRC PATIENTS NOT ELIGIBLE FOR SURGERY

1) 5-FU = CAPECITABINE
2) OXALIPLATIN
3) IRINOTECAN
4) MAbs
   - Anti-VEGF = Bavacizumab (RAS^{MUT})
   - Anti-EGFR = Cetuxmab / Panitumumab (All RAS^{WT})
5) Combination therapy:
   - FOLFOX/XELOX
   - FOLFIRI
   - FOLFOXIRI

} MAbs

- SAMPLES ALREADY STORED
- OUTCOMES ALREADY KNOWN

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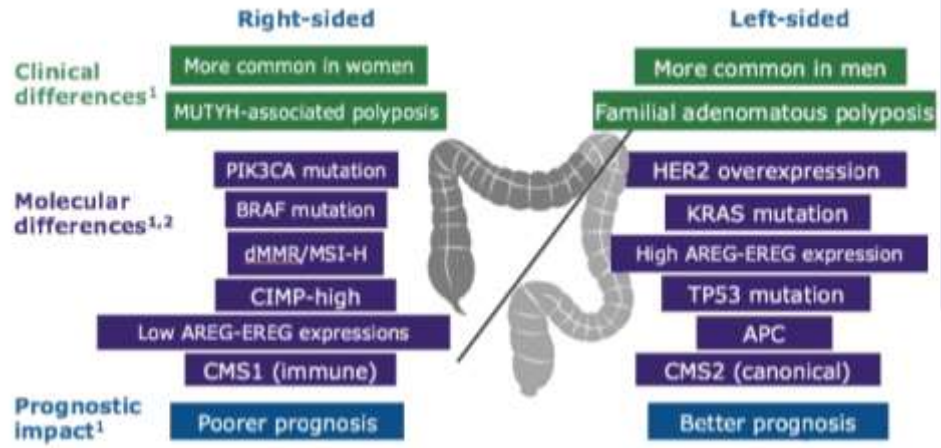
What have we learnt so far?



1. Lee GH, et al. Eur J Surg Oncol 2015;41:300-308; 2. Stintzing S, et al. E J Cancer 2017;84:69-80;
3. Tejpar S, et al. JAMA Oncol 2017;3(2):194-201; 4. Venook AP, et al. ASCO 2016 (Abstract No. 3504).

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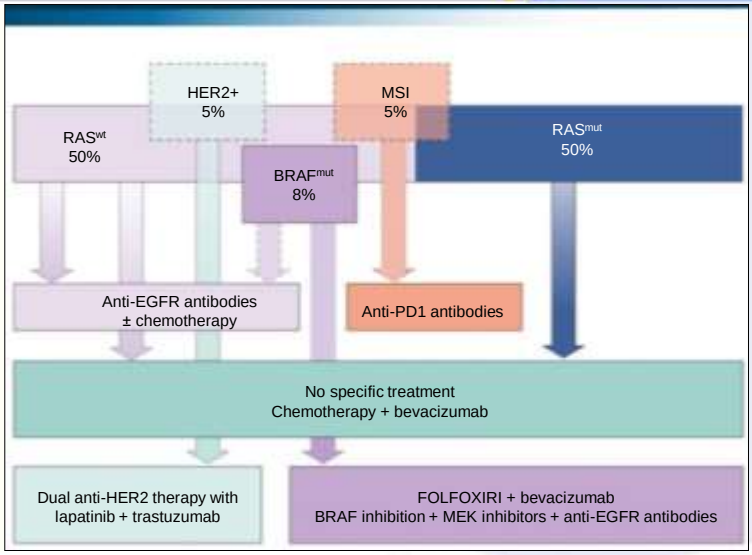

Proposed Landscape of Molecularly Targeted Treatments for mCRC

Punt C, et al. Nat Rev Clin Oncol. 2017;14:235-246.

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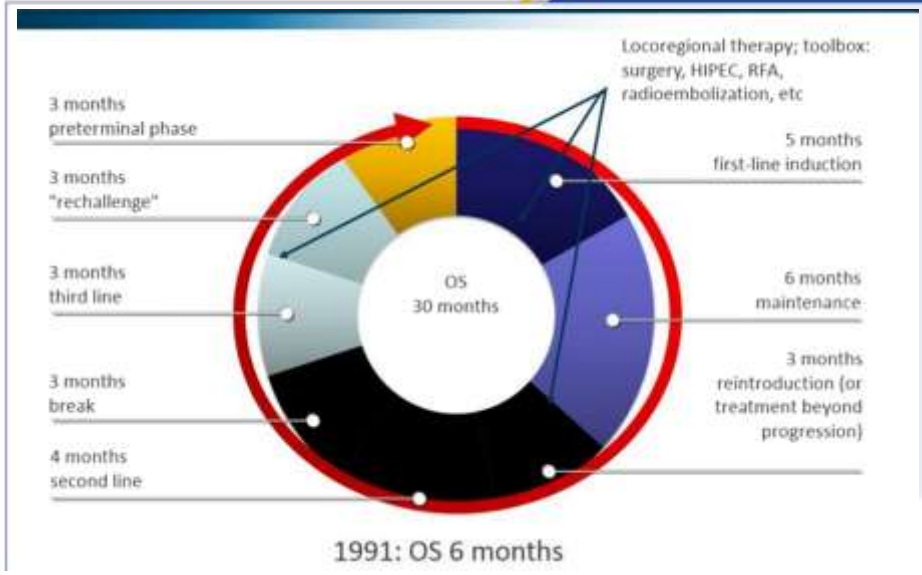

Classical Case of mCRC in 2018: Continuum of Care

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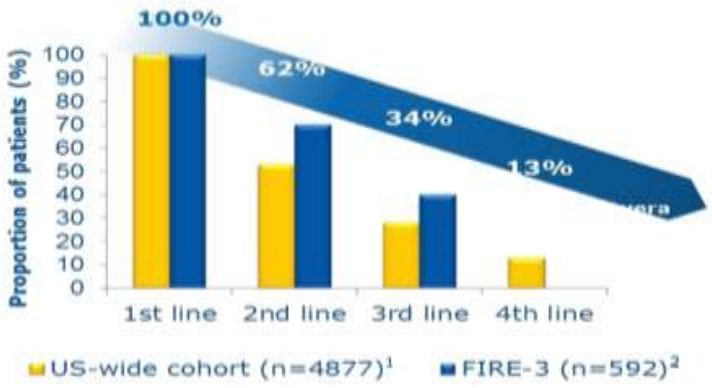
The 1st line treatment decision is the one that counts most: The proportion of patients receiving therapy declines over treatment lines



1. Abrams TA, et al. J Nati Cancer Inst 2014;106:djt371; 2. Modest D, et al. J Clin Oncol 2015;33:3718-3726.

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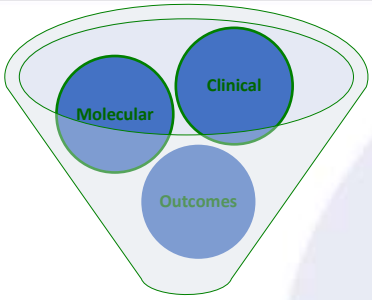

THE NEW STEPS OF CRC THERAPY

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REVERT (taRgeted thErapy for adVanced colorEctal canceR paTients)

Call identifier: H2020-SC1-2019-Two-Stage-RTD

Topic: SC1-BHC-02-2019 – Systems approaches for the discovery of combinatorial therapies for complex disorders

GRANT AGREEMENT n. 848098 — Directorate-General for Research and Innovation People Healthy Lives

#	Participant Legal Name
1	[illegible]
2	[illegible]
3	[illegible]
4	[illegible]
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11	[illegible]
12	[illegible]
13	[illegible]
14	[illegible] — Joint Research Unit (JRU)

6 centri clinici
106 pazienti

- Università Tor Vergata
- Università di Careggi (FI)
- AOUP Giaccone (PA)

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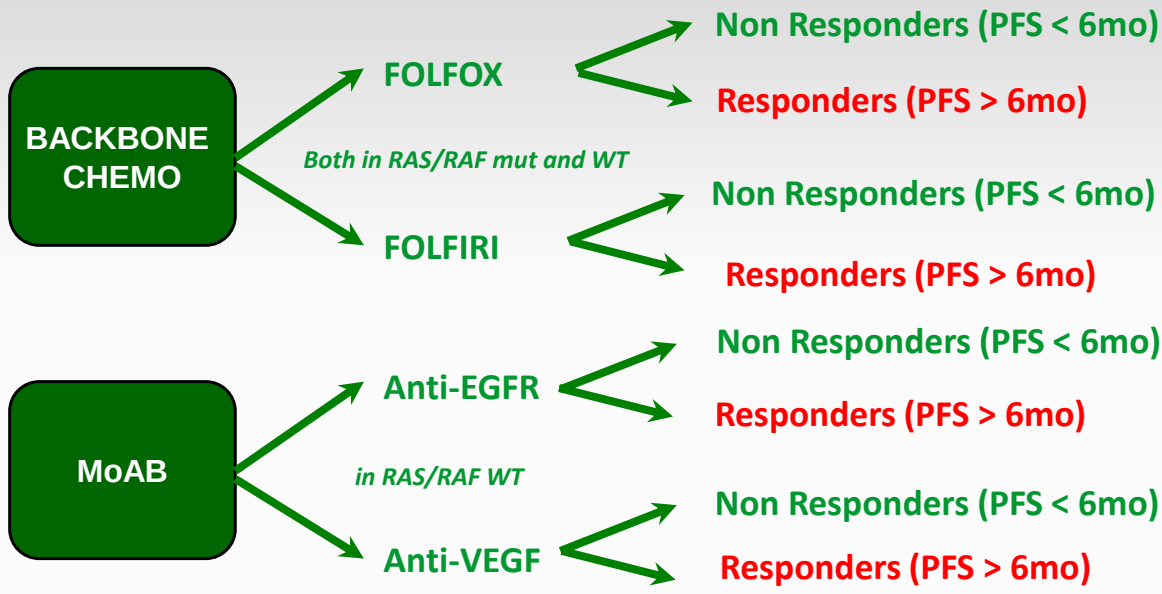
STUDY DESIGN – retrospective phase



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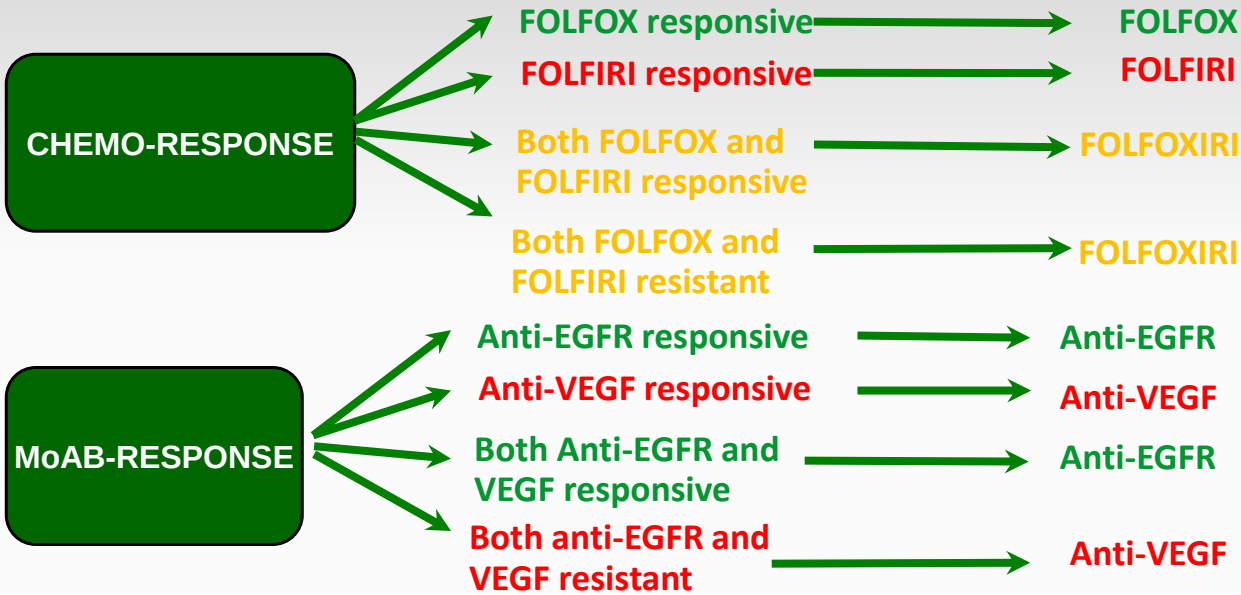
STUDY DESIGN – ML outcome – prosp. phase



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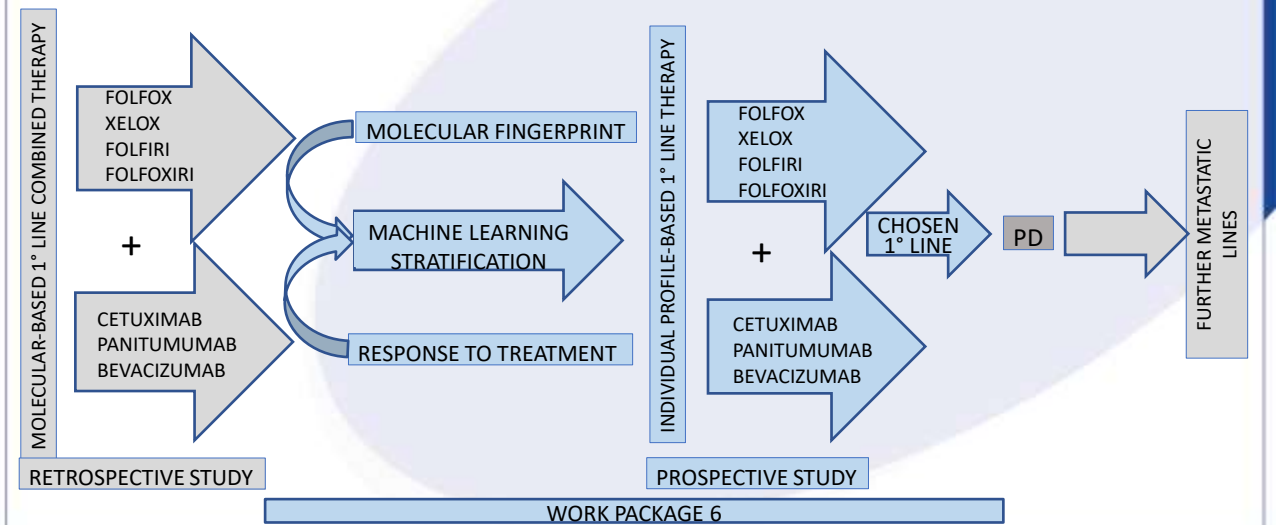

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Study endpoints

Primary endpoint

Progression Free Survival (PFS), including PFS1 and PFS2, defined as the time from enrolment to the first documentation of objective disease progression (defined as per RECIST 1.1 criteria) or death due to any cause, whichever occurs first.

Secondary endpoints

1. Overall survival (OS) defined as the time from enrolment to the date of death due to any cause.

2. Response Rate (RR), defined as the percentage of patients, relative to the total of enrolled subjects, achieving a complete (CR) or partial (PR) response, according to RECIST 1.1 criteria, during the phases of treatment.

3. Early Tumour Shrinkage (ETS), defined as the percentage of patients, relative to the total of the enrolled subjects, achieving a >20% decrease in the sum of diameters of RECIST target lesions.

4. Quality of Life (QoL), will be measured using the EORTC QLQ-C30 questionnaire.

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March 21st FIRST PATIENT ENROLLED

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: University Tor Vergata — REVERT - taRgeted thErapy for adVanced colorEctal canceR paTients

Protocol Section

Record Summary Preview Edit All Help Definitions

Edit **Study Identification**

Unique Protocol ID: University Tor Vergata
Brief Title: REVERT - taRgeted thErapy for adVanced colorEctal canceR paTients
Official Title: REVERT - taRgeted thErapy for adVanced colorEctal canceR paTients
Secondary IDs:

Edit **Study Status**

Record Verification: March 2023
Overall Status: Recruiting
Study Start: March 21, 2023 [Actual]
Primary Completion: June 2024 [Anticipated]
Study Completion: June 2024 [Anticipated]