IC 2013-02 BIO-RAIDs

RAIDs Rational molecular Assessment Innovative Drug selection

Evaluation of biomarkers in advanced stage cervical cancer by an international consortium.

Tumor Stage: 1B2- 4

he research leading to these results has received funding from the European Community's Seventh amework Program (FP7/2007-2013) under grant agreement n° 304810 - RAIDs."

Institut Curie – Paris – September 2013

Context

- RAIDs

« *Rational molecular Assessments and Innovative Drug Selection"*

- EU Project (FP7): 15 partners (clinical academic centres and SME)
- 8 EU countries and 4 SMEs
- 6 Million euro total budget

http://www.raids-fp7.eu/

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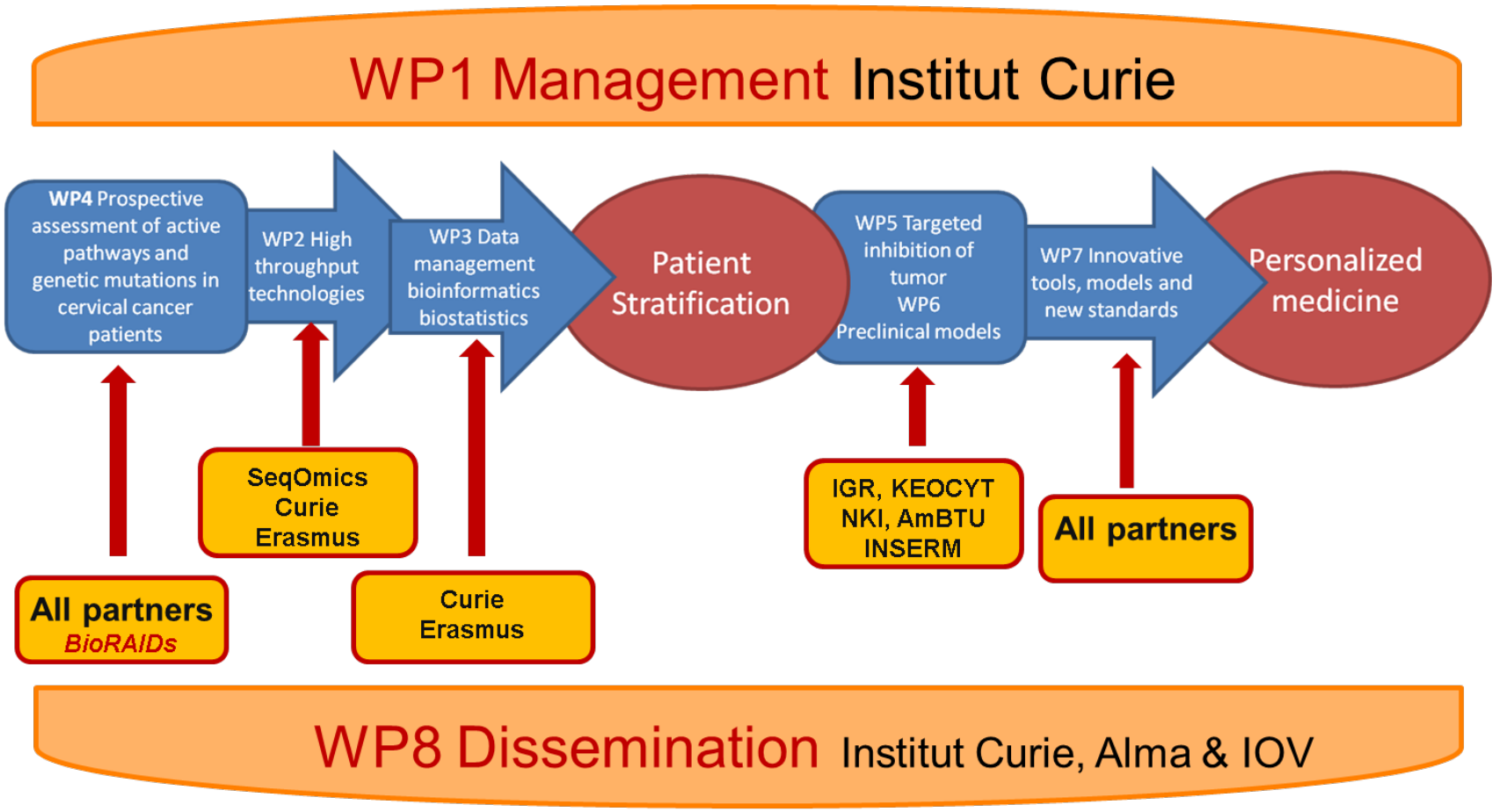
Organization of the RAIDs project



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Bio-RAIDs Trial design:

Rationale and objectives

- Clinical cohort with tissue biopsy and blood sampling
  - before, during and after standard therapies
- Prospective
- Multicentric
- EU
- To allow biomarker assessment

➢ **Indication:** Cervical cancer, not previously treated.

➢ **Primary Objective** :Assessment of dominant mutations and activation of signaling pathways which may allow to predict treatment response.

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Rationale and objectives

➢ **Secondary Objectives :**

- Evaluation of the PFS at 18 months in correlation with dominant genetic and protein alterations.
- Descriptive analysis of standard treatment modalities which are applied in the participating EU countries.
- Descriptive analysis of adverse events (grade 3 and 4).
- Descriptive analysis of the frequency and geographic distribution of dominant molecular alterations.

4- Patient selection criteria (1)

➢ **Inclusion criteria:**

1) The patient has not been previously treated.
2) Tumor stage IB2 to IV (FIGO); all histological subtypes (with the exception of neuro endocrine tumors).
3) Cervical tumor confirmed by MRI on T2 weighted imaging (+ ultrasound gel in vagina).
4) Possibility to transfer images by CD-ROM (format DICOM 3.0 or higher).
5) The tumor needs to be biopsiable (one biopsy represents at least 3 fragments and is mandatory at the start of the trial).
6) Age ≥ 18 years.
7) WHO Score : 0-2.
8) Life expectancy > 6 months.
9) Patient is eligible for standard therapy (according to references of each centre).
10) Patient has health insurance.
11) Patient has agreed to and signed an informed consent.

Logistics

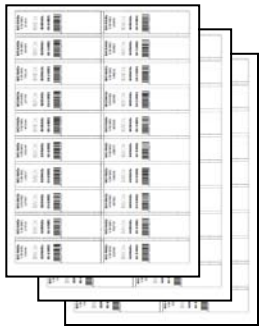
Verification of eligibility by investigator
And signature of informed consent

↓

Patient Inclusion via eCRF by investigator

↓

Attribution of inclusion n°
|_1_|_0_|_1_| |__|__|__|
N° centre N° d'ordre
+
Attribution of n° of KIT - labels



BIO-RAIDs
9 00 0001
173728

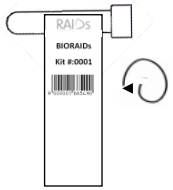
9 00 0001 173728

Fixed Sequence (9 00)

Number of kit (4 digits)

Variable Sequence unique (6 digits)

Identification of cryotubes : 2ml



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RAIDs

Rational molecular
Assessment
Innovative Drug
selection

RAIDs is on cervical cancer only

Future PERSPECTIVES

- Information exchange + potential collaborative efforts
  - Genetic comparison with other gynae tumor types: « Mullerian structures »
  - Other biological techniques to be explored in collaboration
  - Translational input into trials
  - Budgeting of future Translational Academic projects
    - Combinations between targeted therapies + Micro environment / vaccines
    - Large consortium: networks needed
    - SMEs
    - Bio informatics groups

EORTC
European Organisation for Research and Treatment of Cancer

SEVENTH FRAMEWORK PROGRAMME

Thank you for your attention

Questions ?

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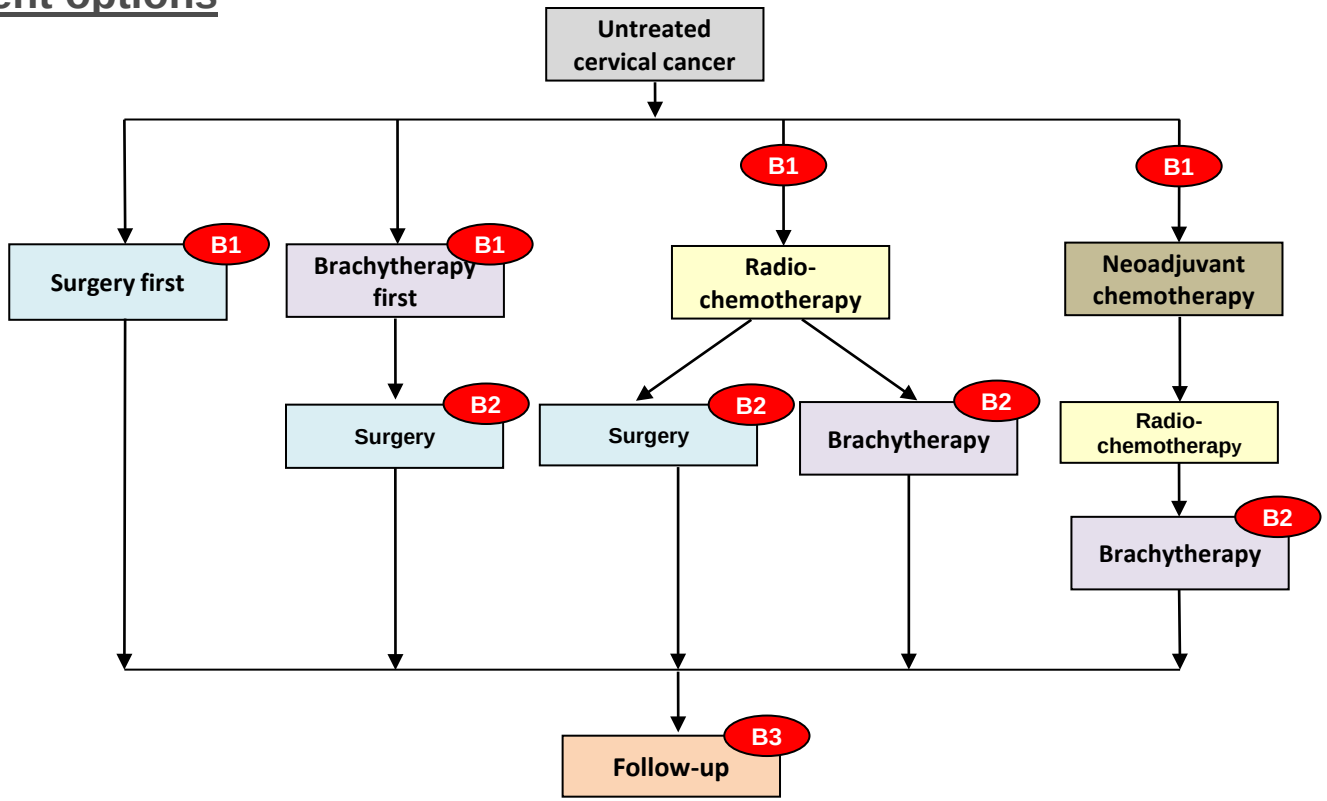
BioRAIDs Study flow chart and sampling

- **Treatment options**



Please view recommandations (in clinical protocol section 5)

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