Institute of Oncology
Chisinau

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RAIDs
Rational molecular
Assessment
Innovative Drug
selection

BIO-RAIDs

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

Tumor Stage: 1B2- 4

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Institut of Oncology – Chisinau – March 17, 2014

Plan

1. Context
2. Rationale and objectives of the trial
3. Methodology

1- Context

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1- Context

➢RAIDs

« *Rational molecular Assessments and Innovative Drug Selection”*

➢EU Project (FP7): 15 partners (clinical academic centres and SME) conjointly form the RAIDs consortium.

➢8 EU countries and 4 SMEs

“SME - small to medium-sized enterprise, a company with no more than 500 employees”.

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

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1- Context

•RAIDs is a multidisciplinary approach which integrates genomic, proteomic, and viral genotyping as well as immuno-histochemical analyses of cervical tumor biopsies and patient blood samples.

•Objectives are to

- Harmonize clinical practice for diagnostic and therapeutic purposes.
- Develop new tools for early diagnosis.
- Identify biomarkers of prognostic and predictive value for response or no response to standard therapy.
- Learn to stratify patients according to molecular profiles, allowing inclusion in personalized treatment protocols.

Workpackage 4 [grant agreement number: 304810 / FP7 – HEALTH – 2012 – INNOVATION – 1 program]

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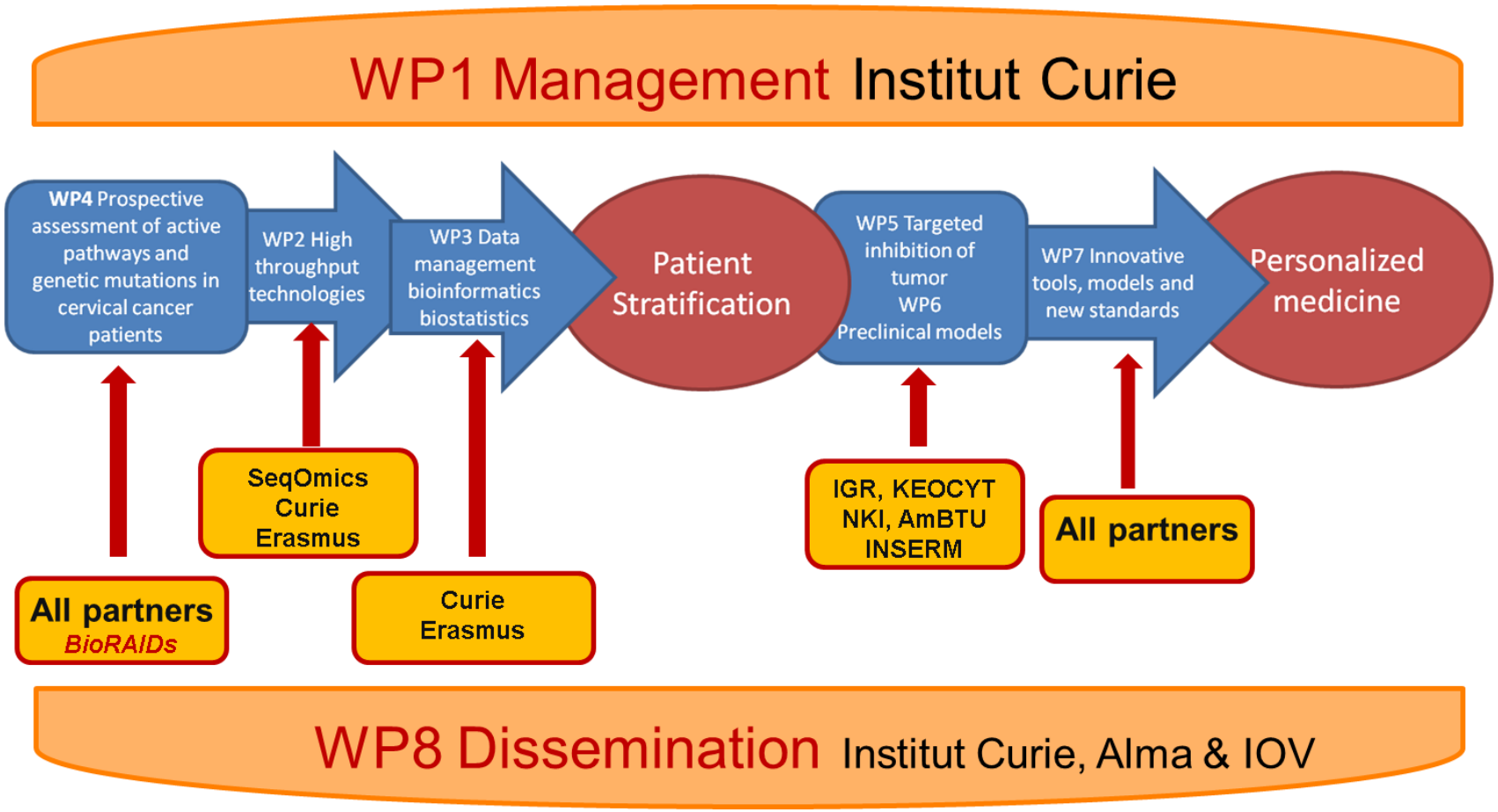
Organization of the RAIDs project



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2- Rationale and objectives of the trial

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2- Rationale and objectives of the trial

• Cervical cancer is the second cause of cancer related mortality of women worldwide

• In the EU 34 000 new cases ad more than 16 000 deaths are registered each year.

• There remains a disparity in the incidence and mortality rates of cervical cancer in the larger EU arena of 27 member states.

- The Incidence is higher in the more recent member states (Central and Eastern Europe)
- The Mortality in Moldova and Romania is ≈ 11x the mortality rates of Finland.

2- Rationale and objectives of the trial (2)

- Despite the early enthusiasm of preventive HPV vaccination it appears mandatory to pursue screening efforts, since:
  - The first effects of preventive vaccination on the incidence of cervical cancer are likely to become visible 20 years from now
  - The people most « at risk » for a variety of reasons will not have been vaccinated

2- Rationale and objectives of the trial (3)

Molecular analysis of tumor biopsies and blood samples
at predefined time points
to allow biomarker assessment by an international consortium.

➢**Indication:**

Cervical cancer, not previously treated.

➢**Primary Objective :**

Assessment of dominant mutations and activation of signaling pathways which may allow to predict treatment response.

2- Rationale and objectives of the trial (4)

➢**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.

3- Methodology

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3- Methodology

- **Interventional trial – without medication**
- **Prospective**
- **Multicentric**
- **EU**

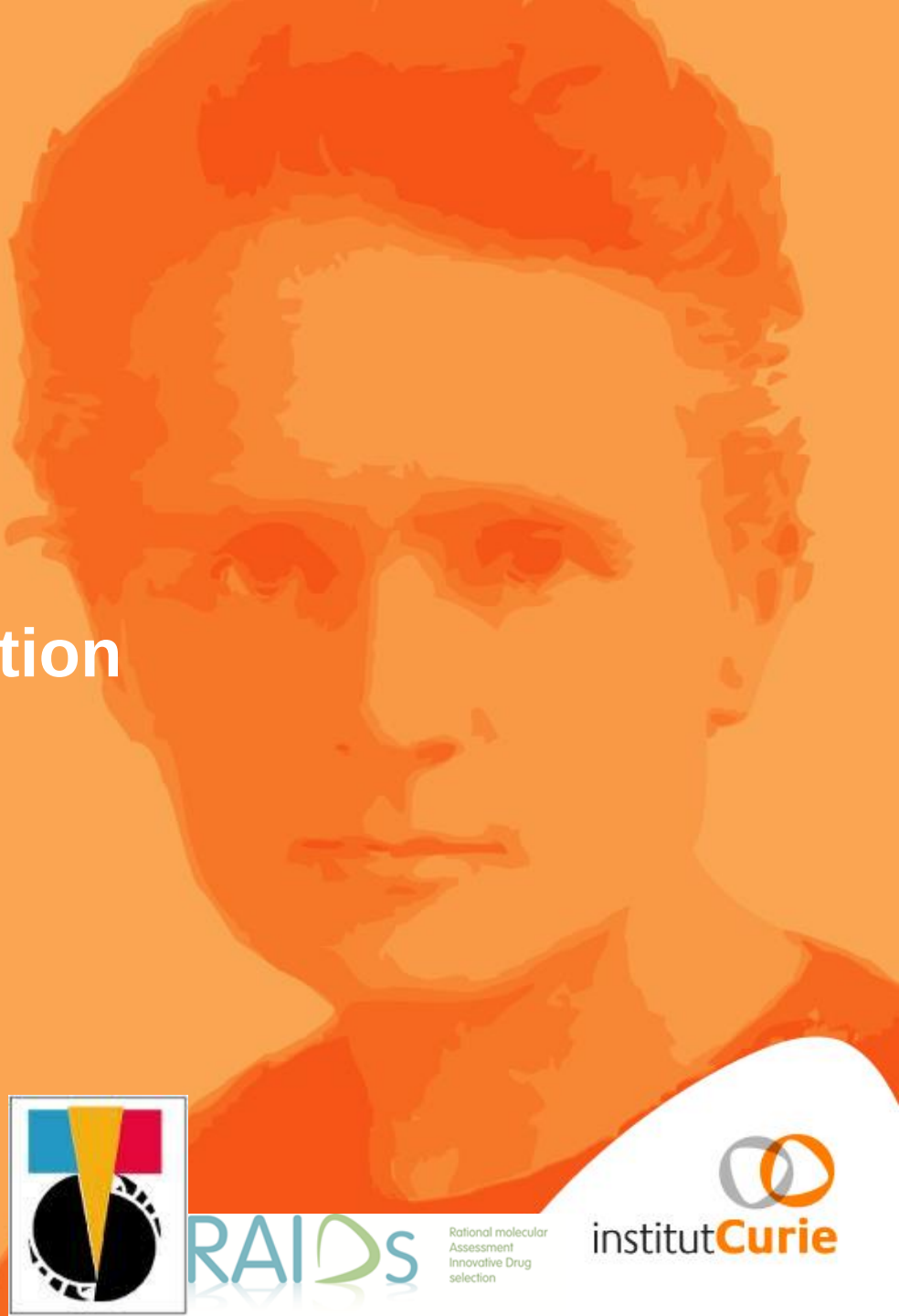
7 countries:	Serbia,	Romania,	Moldova,	France,	Holland,	Germany,	Belgium
700 patiens:	80	160	60	150	90	90	70

Period of inclusion : 3 years

Follow up of patients after end of treatment : 18 months

Total Duration of study **:** 5 years

Thank you for your attention



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