

The EURAMOS logo features the word "EURAMOS" in a blue, sans-serif font. A white, stylized swoosh or orbital path curves around the letters from the bottom left to the top right.

EURAMOS-1

Accomplishments and achievements

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Supported by the European Science Foundation (ESF) under the EUROCORES Program European Clinical Trials (ECT), through contract No. ERASCT-2003-980409 of the European Commission, DG Research, FP6

The logo for the European Science Foundation, consisting of the words "EUROPEAN SCIENCE FOUNDATION" stacked vertically in a bold, sans-serif font.

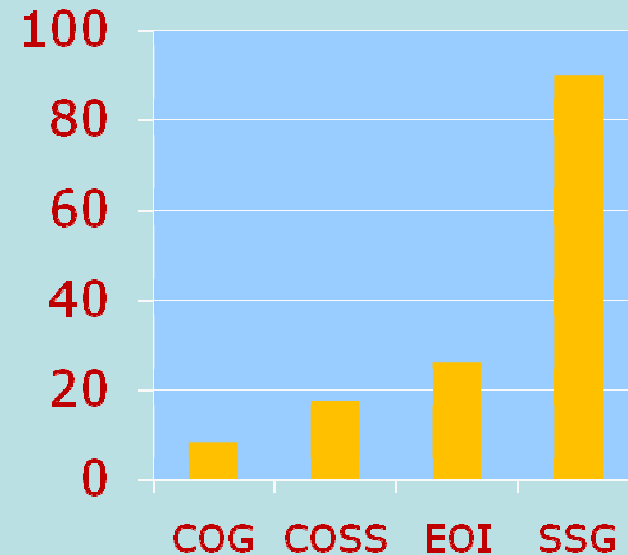
EUROCORES Programme
European Collaborative Research

2002



- Four osteosarcoma intergroups; Similar but not identical treatment, all planning their next protocol
- SIOP (Brisbane) meeting in 2002: EURAMOS collaboration established
- Paralleled in time with the implementation of the EU-Clinical Trials Directive EC 2001/20
- **Three-year process** to resolve regulatory and organisational issues
- Mandatory support from the European Science Foundation (ESF)
- The obvious salvage question only possible with broad international collaboration.

Time needed (years) to ask the salvage question



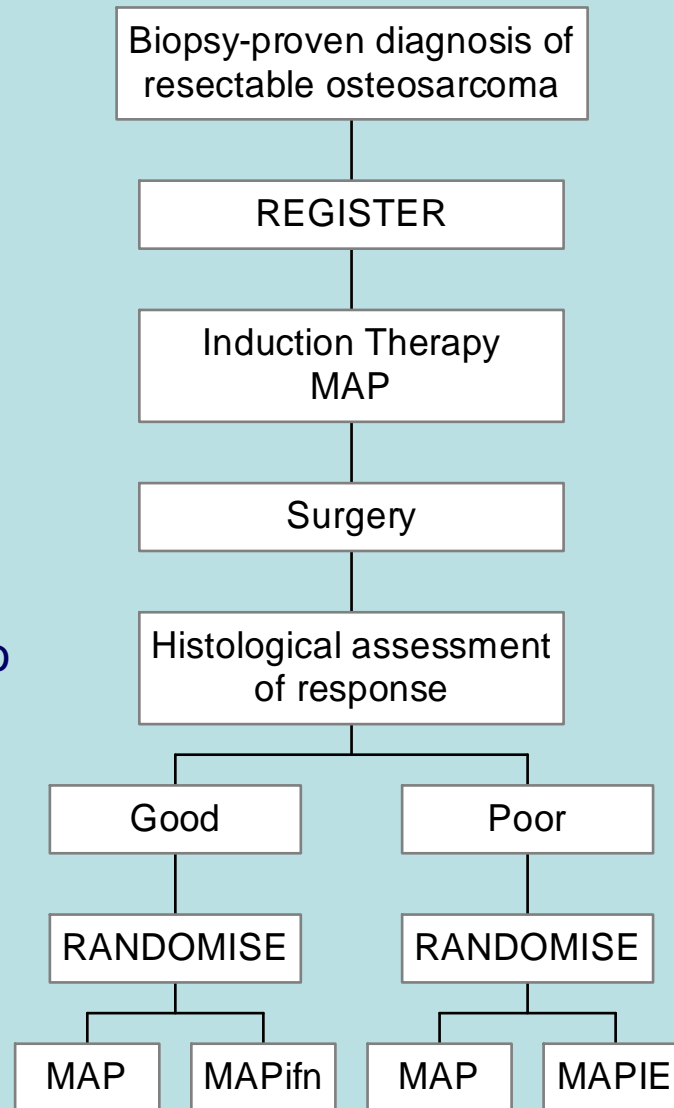


EURAMOS-1

- **Open for all patients** with resectable high-grade osteosarcoma

- The trial takes into account the **strong prognostic value of tumor response** to preoperative chemotherapy and divides patients accordingly

EURAMOS 1



Euramos-1

- 4 y anticipated accrual time (**1400 pts**). Covers a population >0.5 billion people. 90 % (**1260**) expected to be randomized

Objectives

- Event-free survival
- Overall survival
- Quality-of-life



Establish a common Infrastructure

- Sponsorship: Delegation of responsibilities through signed agreements
 - One Common Data Center
 - Group-wise Data Centers
- Common Drug supply: contract issues
- Pharmacovigilance: One Safety Desk
- One FWA per coordinating center



Status by Feb 2010

Registrations (n=1723)



- 1723 patients recruited from 301 institutions in 15 countries
- 987 patients are randomized
 - 65 % effectively randomized (late randomization and high substitution)
- Continuing accrual to fall 2010 (early 2011); 2000 pts recruited (40 last month)



Conclusion

- Major effort to establish an appropriate structure for randomized trials in osteosarcoma:
 - Common infrastructure
 - Accrual time of 3-5 years (350 pts/year)

Collaboration beyond intergroups mandatory for future randomized trials

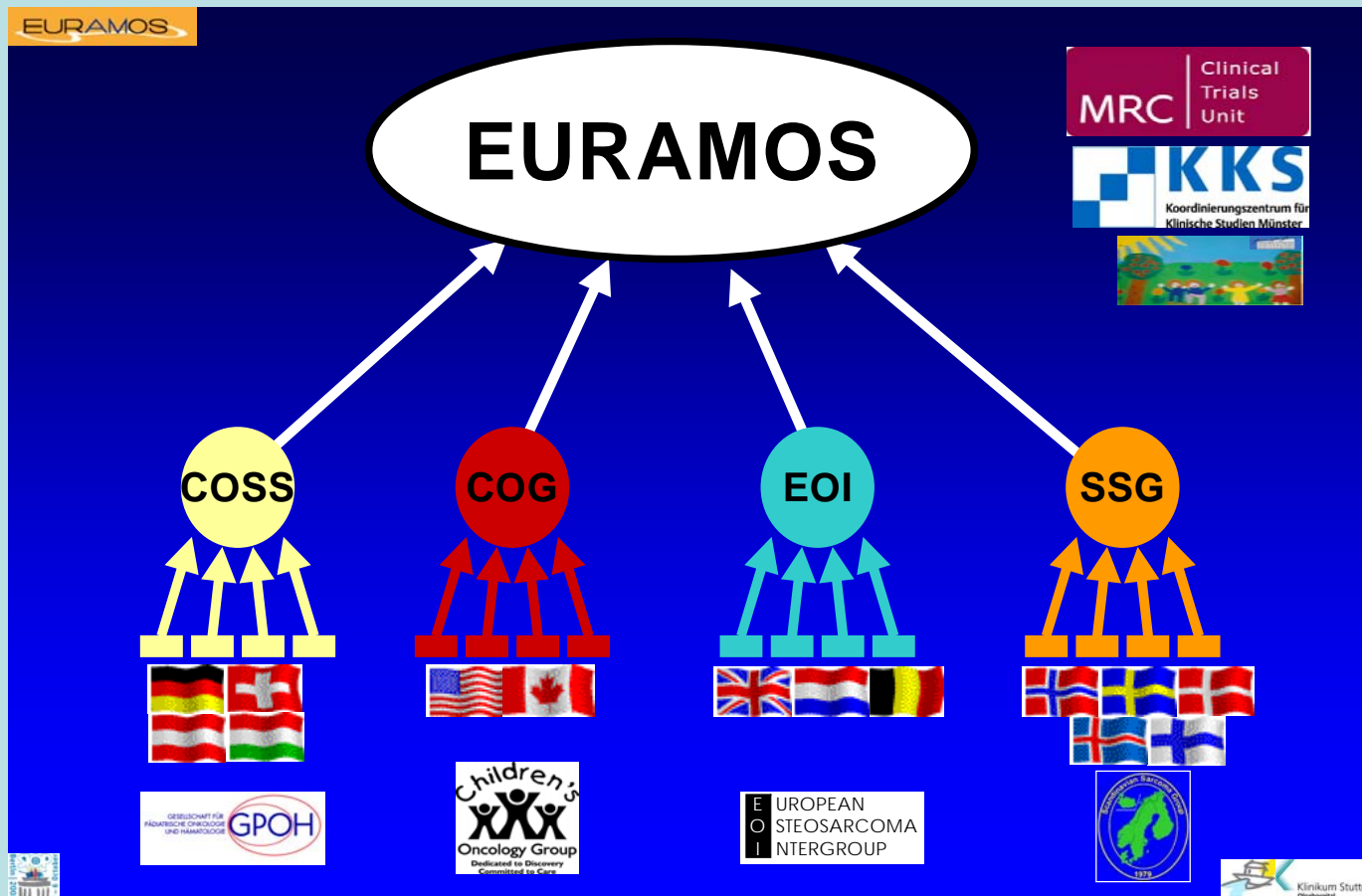
- First multinational randomized trial launched in Europe after the EU-directive: Model trial and positive attention for the Euramos collaboration (ESF important support)



Next steps

- Continue with EURAMOS as a structure for future randomized trials in Osteosarcoma (3 years of work)
- Most important to move on with a trial for primary cases – EURAMOS-2
- Ambition to move from a protocol to a program:
 - biology and relapsed trials.
 - Invite more study groups to join EURAMOS
- Funding issues for future academic trials not solved. Funding of EURAMOS-1 a unique case. Aim to have a more coordinated application/funding processes among centers and nations in multinational academic trials

Thanks to all collaborators



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