CHEMGENEX

EUROPE

# BioTuesday, March 2, 2010

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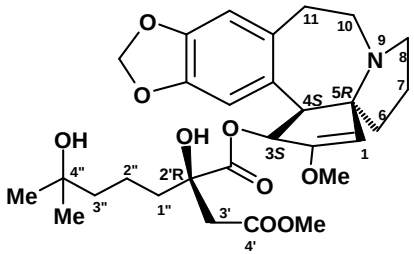
PHARMACEUTICALS

# History - Past




homoharringtonine

**Chinese medicine for the treatment of myeloid leukemias – 1970s**

**US National Cancer Institute research program – 1980s**

**Efficacy in myeloproliferative disorders**
**GMP issues with the natural extract**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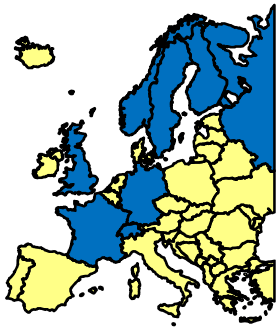
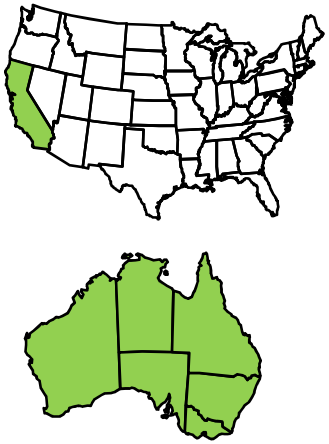
# History

**Oncopharm: semi-synthetic formulation**



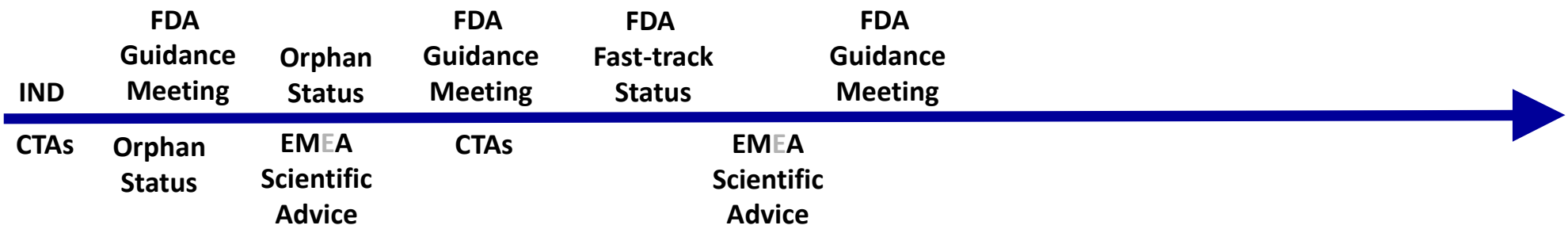
**Purified natural formulation**



**Partnership: 2005**

# Similarities and differences

## CMC, non clinical and clinical development for both EU and USA:



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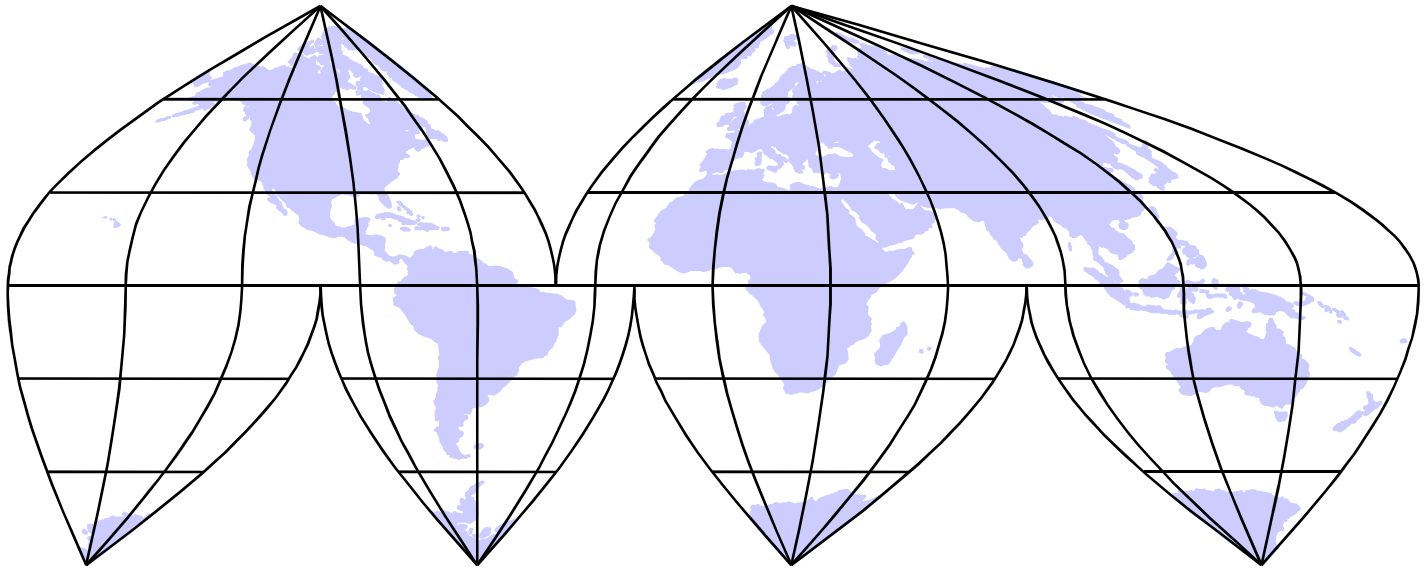
# EU / US / Asia

**CMC, nonclinical:** no issue, whatever the location

**Clinical in an ultra-orphan indication:** 32 clinical sites over 11 countries

sponsor's clinical team in the US and in EU



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# ChemGenex affiliate in EU: Why and When?

- For the conduct of clinical trials in EU member states:
  - the sponsor or its legal representative must be established in an EU member state
- For Orphan Drug Designation by EMEA:
  - the sponsor must be established in an EU member state
- For EU Marketing Authorization Application:
  - the applicant must be established in an EU member state



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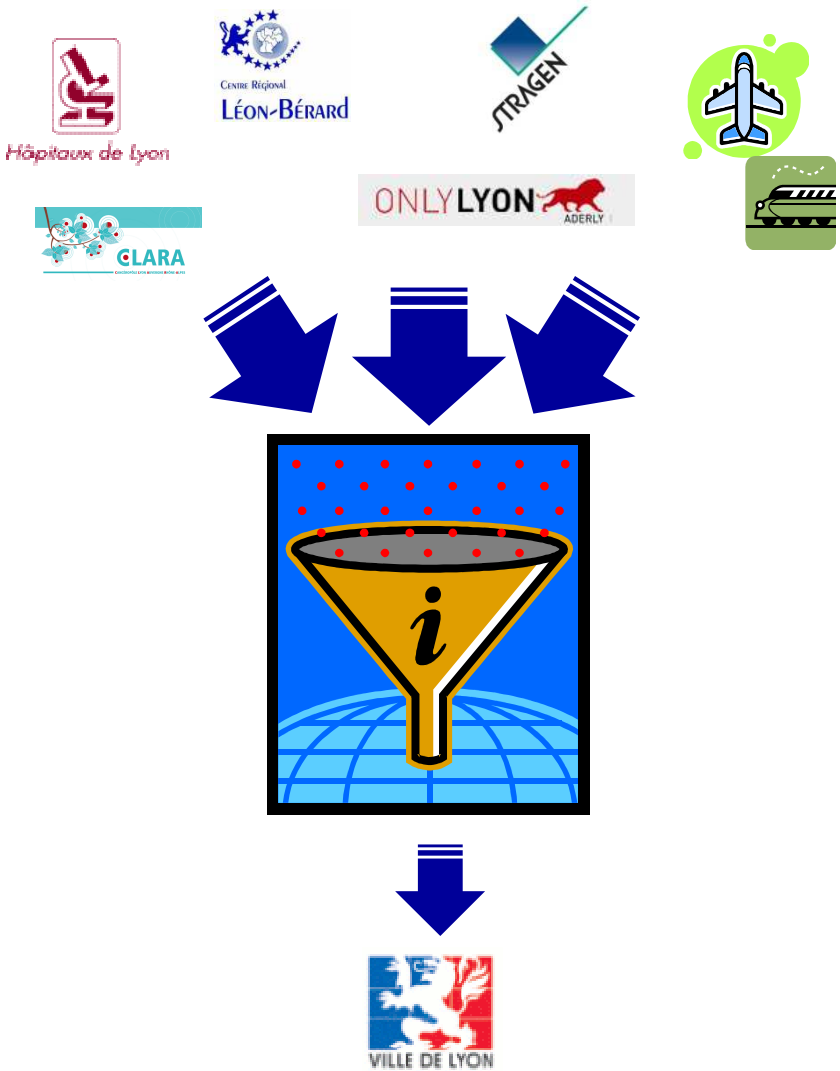
# … and Where?



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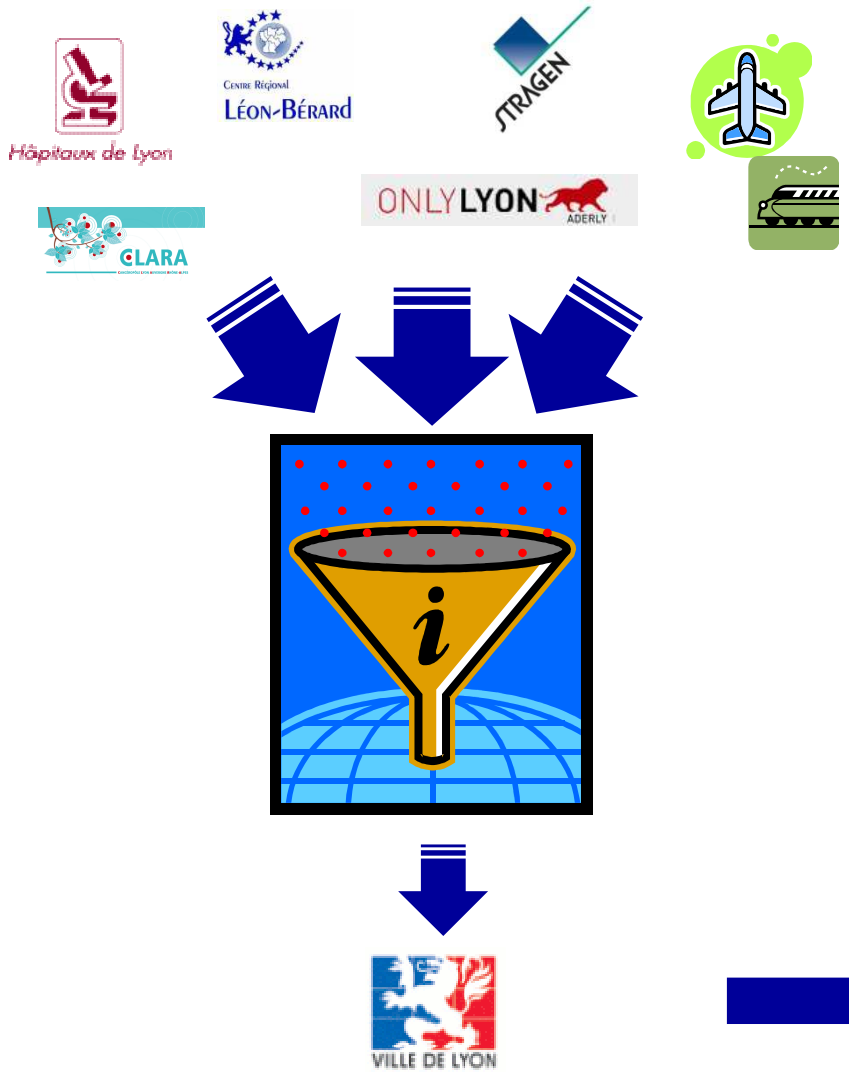
# ChemGenex Europe, as a result of the project needs

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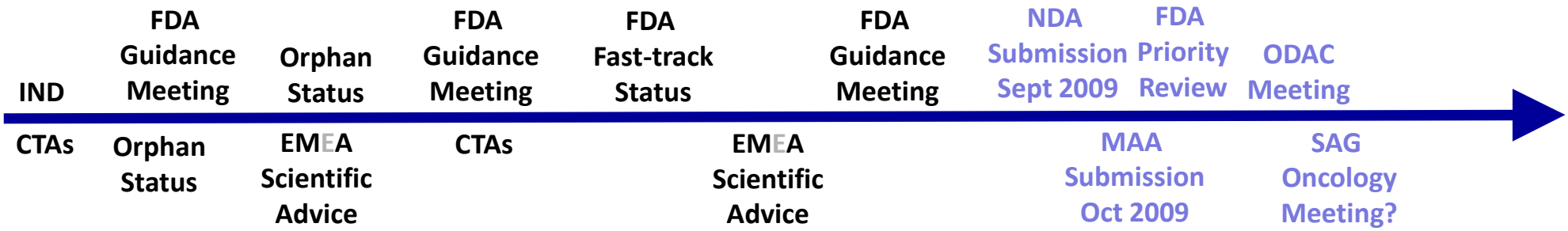
# Success story?



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# Conclusion

- Globally, similar requirements for the registration of a new drug in the US and the EU regions
- Local staff with appropriate skills is nevertheless required for managing the differences
- Efficient synergy of a US+EU project team without doubling efforts