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Personalized Medicine Today and Tomorrow

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Vice President
Research and Development

Emerging Markets and Molecular Diagnostics
Affymetrix Inc.

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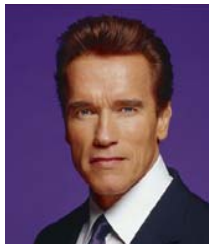
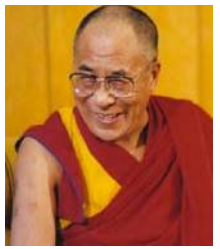
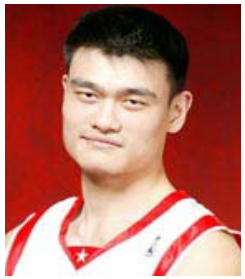
Personalized medicine, evidence-based medicine





Medical treatment based on an individual's phenotypic, clinical, genetic and molecular information.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Personalized medicine today

	Save Lives	Save Dollars
Whole Blood Glucose – Diabetic Control	✓	✓
Near Patient Coagulation – Coumadin Mgmt	✓	✓
PSA – Prostate Cancer Detection	✓	✓
T4/TU/TSH – Thyroid Management	✓	✓
Lipid Analysis – Coronary Disease Prevention	✓	✓
Troponin Assays – M.I. Triage	✓	✓
Strep Tests – Antibiotic Use		✓
* HercepTest – Breast Cancer – Therapy Selection	✓	✓
*Gleevec – Chronic Myelogenous Leukemia	✓	✓
Iressa – Non-Small Lung Cell Carcinoma	✓	✓

***Used genomic technology in development and/or clinical trials**

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Personalized medicine today

First FDA cleared microarray-based diagnostic test

December 2004

Roche AmpliChip™ CYP450 Array

Roche AmpliChip™ CYP450 Test (IVD)

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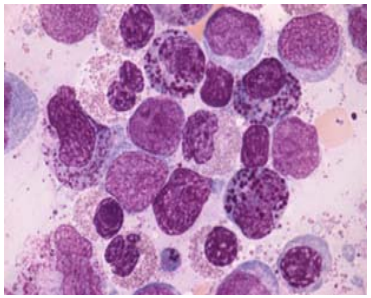
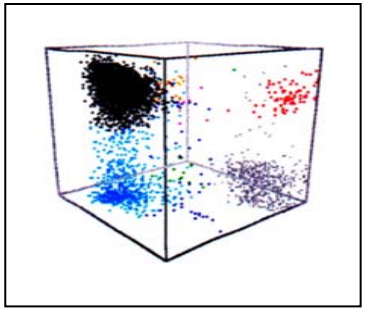
Current methods of leukemia classification: Combination of methods

Morphology

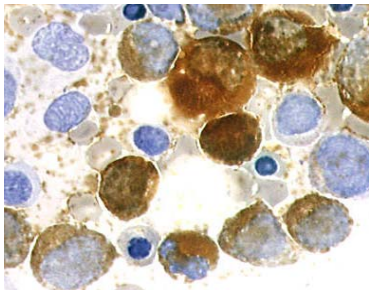


Cytogenetics

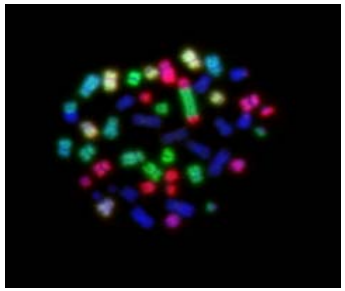
Immunophenotyping



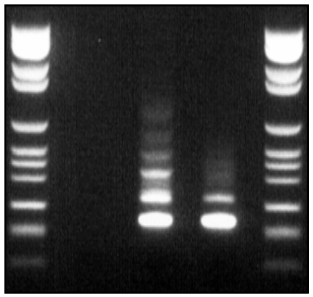
Cytochemistry



FISH



Molecular Biology



T. Haferlach MD, Chief, Grosshadern Leukemia Clinic, Munich

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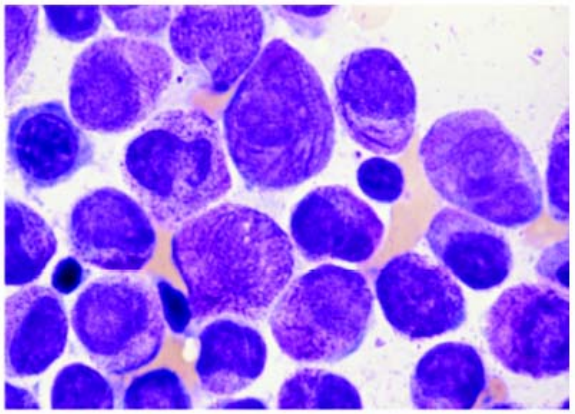

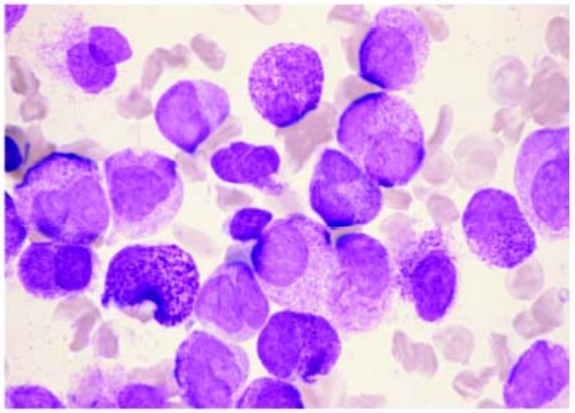

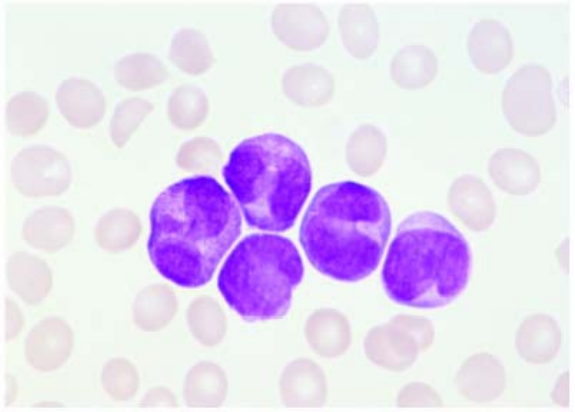

AML M3 with t(15;17)

Same diagnosis

AML M3 variant with t(15;17)

Haferlach et al., 2005

Personalized medicine tomorrow: Two distinct subtypes of AML with t(15;17)

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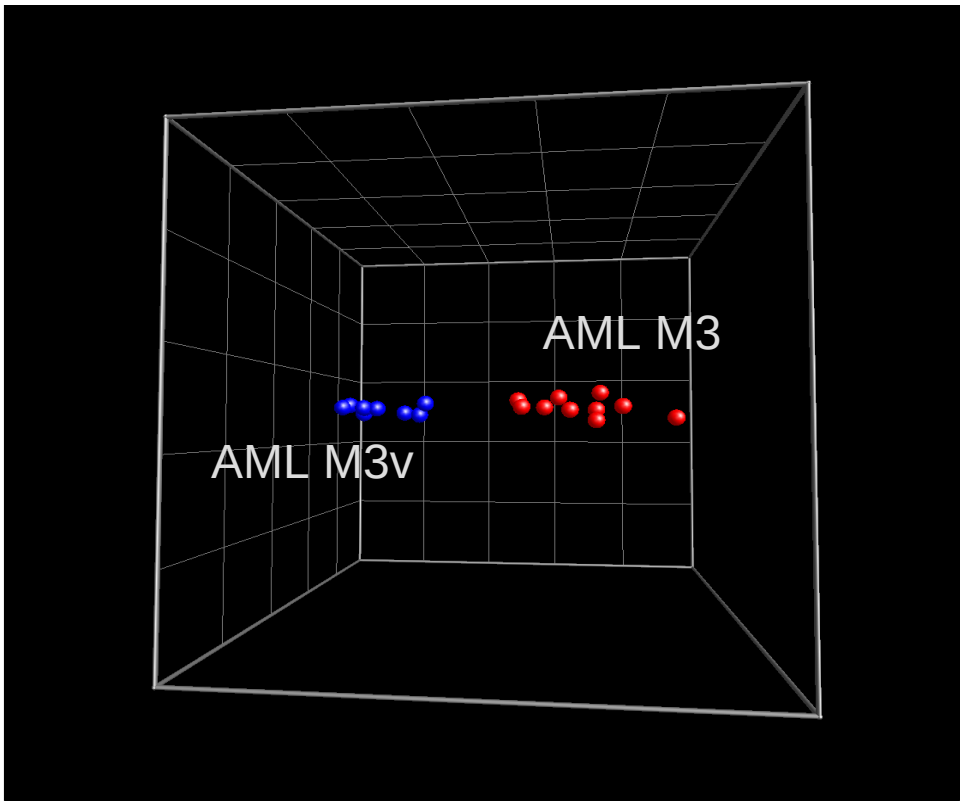
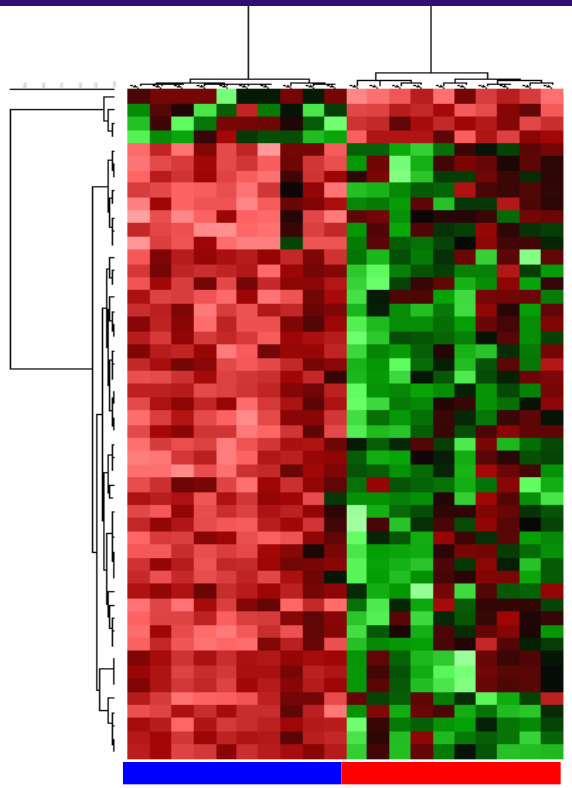
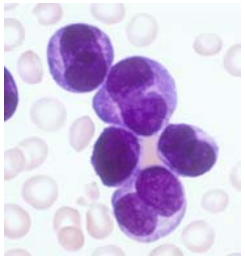
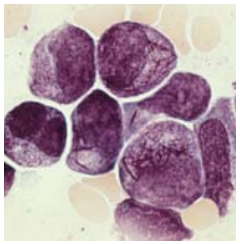


Different disease subclass





AML M3v



AML M3

Haferlach et al., Semin Hematol, 40, 281-295, 2003

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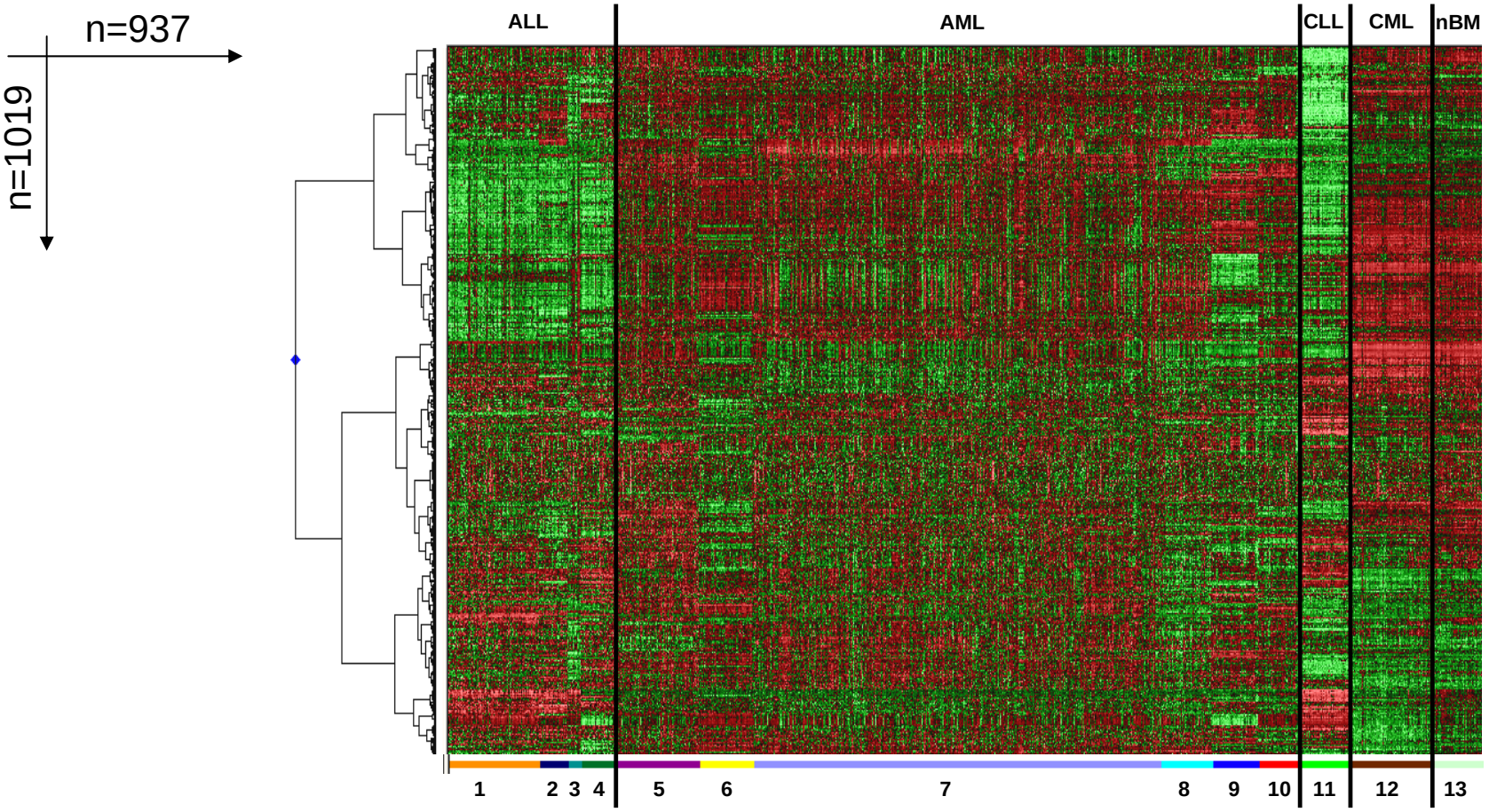
Distinct gene expression patterns in clinically relevant leukemia subtypes



1: precursor B-ALL
2: ALL with t(11q23)/*MLL*
3: ALL with t(8;14)
4: precursor T-ALL
5: AML with complex kt.
6: AML with inv(16)
7: AML normal/other
8: AML with t(11q23)/*MLL*
9: AML with t(15;17)
10: AML with t(8;21)
11: CLL
12: CML
13: nBM

Haferlach et al., 2005

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Activities that will increase access to personalized medicine

- >20 microarray-based diagnostic products

  in pipeline
- Community recognition of value of harmonization of terminology, controls, protocols, best practice guidelines and electronic information management systems
  - Increasing amount of clinically relevant genomic information available
  - Anticipated increase in cost of care
  - Practical, achievable – crosses disciplines and is mutually beneficial

One example
The External RNA Controls Consortium

- 175 members, 92 organizations, 14 countries
  - Government, regulatory, academic laboratories and biotechnology, pharmaceutical and diagnostic companies
- Ways of working
  - Volunteer organization
  - Open to anyone with an interest in working together
  - Consensus based decision making
  - Publish final results as a group by the group
- Goals
  - Develop well-characterized standard controls for multiple genomic technology platforms e.g. microarray, RT-PCR
  - Develop protocols for multiple applications, research and clinical laboratory
- First Deliverable, August 2006
  - (MM16) Use of External RNA Controls published by CLSI

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Government can advance personalized medicine through key policy areas

Encourage and support Genetic Information Non-discrimination Act

Mechanism for complementary FDA and CMS/CLIA roles/policy

Develop regulatory and reimbursement pathways for novel diagnostics and therapies that allow timely and adequate coverage

Grants supporting public/private partnerships for standards efforts, forums and workshops

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Summary

- Personalized medicine is being practiced now and many more applications are in development
- Comprehensive genetic and clinical information could result in more effective and efficient diagnosis and treatment
- Government can stimulate progress through key policy initiatives
- International harmonization benefits patients, physicians, test and drug developers, regulatory bodies, trade and commerce