

NCT NATIONALES CENTRUM FÜR TUMORERKRANKUNGEN HEIDELBERG

BioQuant MODEL base of LIFE

iPH Institute of Pathology Heidelberg

TIGA HAMAMATSU TISSUE IMAGING & ANALYSIS CENTER

Opening of the 3rd European Conference on Whole Slide Imaging

Niels Grabe

How to deal with transformations?

December, 2012, Volume 10, Number 4

Dual Transformation: Rebuild Your Core While You Reinvent Your Business Model

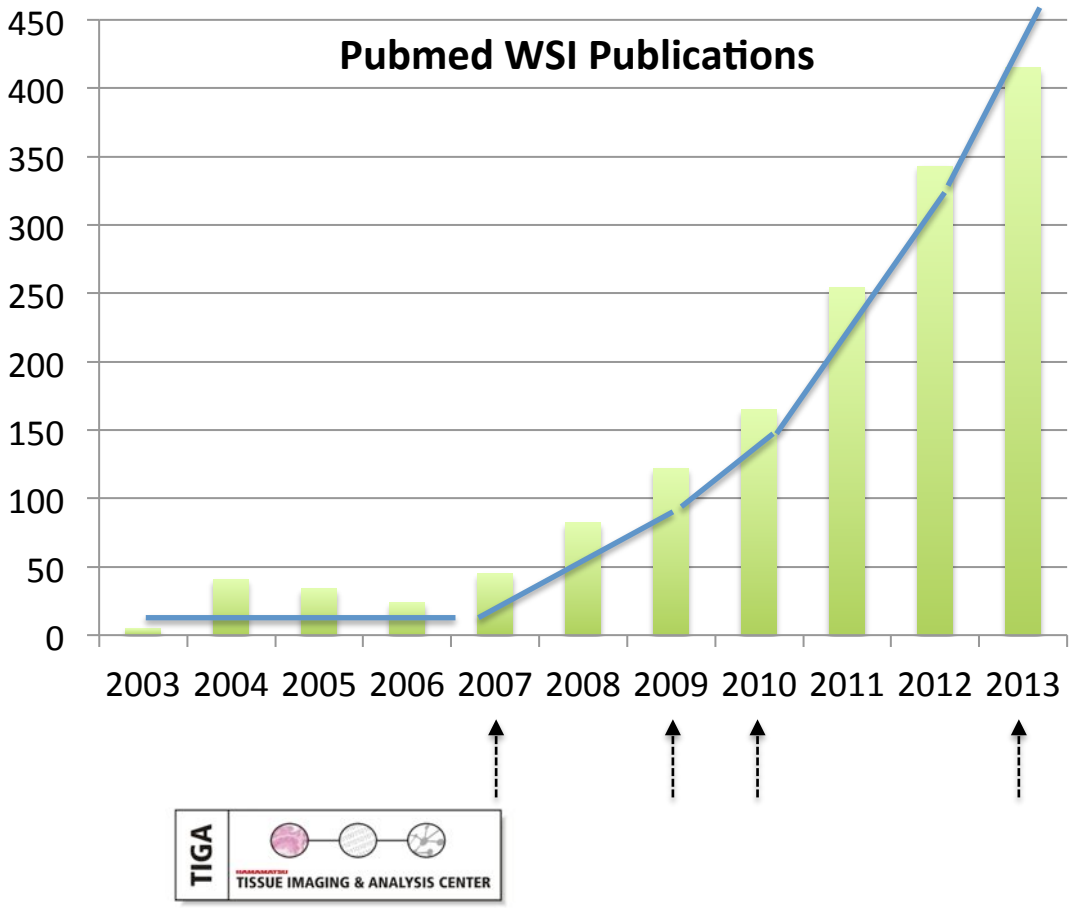
By Clark Gilbert, Matthew Eyring and Richard N. Foster

Sooner or later, most companies will need to reinvent themselves in response to disruptive market shifts, technologies, or start-ups. But how? Can a new business model quickly replace all the revenue an incumbent has lost to market upheaval?

Only in rare instances, says our article in the new issue of *Harvard Business Review*. That's why we propose that companies under assault pursue two distinct but parallel efforts: "Transformation A" should reposition the core business, adapting it to the altered environment. "Transformation B" should launch a separate, disruptive business that will be the source of future growth.

Harvard Business Review, Dec 2012

Scientific Transformers



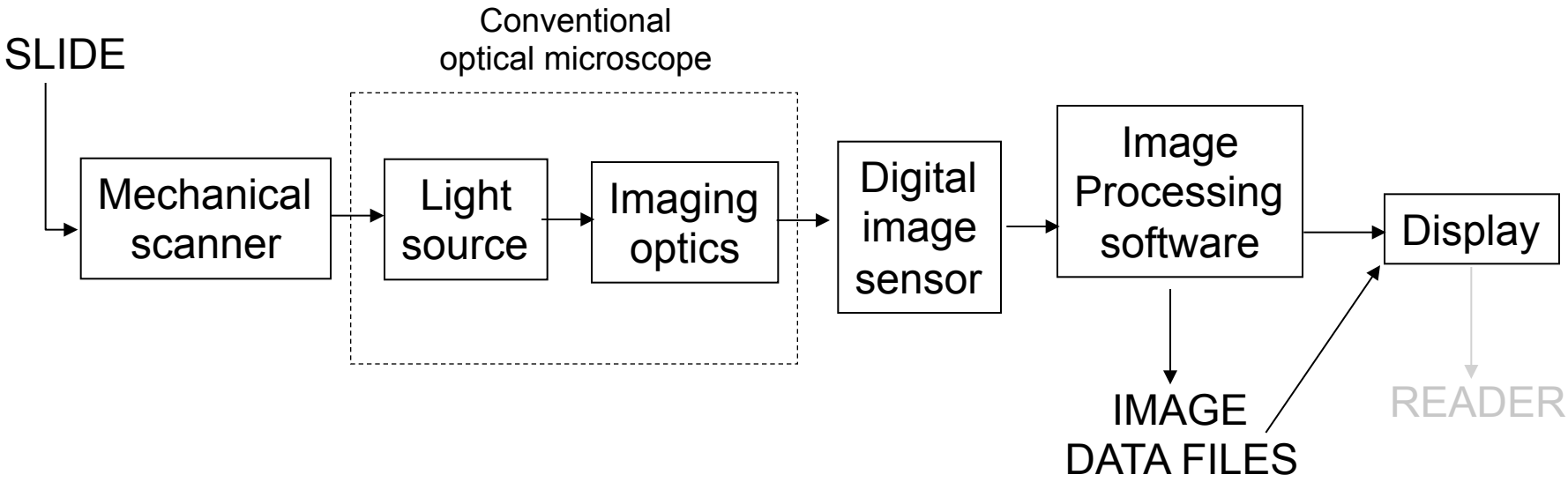
WSI is Transforming

- Transforming research in many fields:
  - Bioinformatics
  - Biology
  - Medicine
  - Medical Systems Biology + Systems Pathology
- Transforming biomarker analysis
  - Clinical studies
  - Regulatory studies
  - Multi-dimensional
- Transforming HE & IHC based diagnostics

- The question is not if: the question is how?
- How will you have to adapt?
- What chances will emerge for you?

Real Transformers = Companies !

FDA on Whole Slide Imaging (=>*Transforming Diagnostics*)



- Microscope one component of the system
- Image acquisition, processing and display new technology for this intended use
- Diagnostic for neoplastic disease
- WSI systems can not be considered Class I exempt

21 CFR 864.9 Limitations of exemptions from 510(k) (a few)

Exemption only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality

- Different fundamental scientific technology
- IVD intended for use in diagnosis, monitoring or screening of neoplastic diseases

How does FDA plan to ensure the safety and effectiveness of digital pathology devices?

- Require **analytical and clinical studies** to objectively and precisely validate performance
- Knowledge of the risks, benefits and limitations
- Standardization
- Postmarket studies

Summary

- FDA recognizes that the technological advances associated with WSI make its use a reality
- WSI systems are not Class I exempt and are therefore, subject to premarket requirements
- Current IVDs that utilize digital imaging for limited applications are not applicable to the WSI paradigm
- Digital mammography may provide useful lessons but does not address all of the concerns for WSI
- Our goal is to gain information about the technology in order to ensure safe and effective use

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Technology Research (Systems Pathology)

Translation

COMBI DIGITAL PATHOLOGY PLATFORM

Large-scale Biomarker Quantification in Routine and Clinical Studies

Technology

BMBH BioMaterialBank Heidelberg

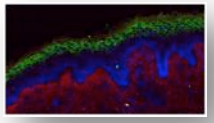
Large-Scale Tissue Banking

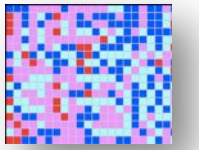
WSI

IVD + WSI

„House“ of Medical Systems Biology

Computational
multi-scale modeling





Molecular
analysis

Testable tissues
(3D Cell culture)

Spatial/microscopic
tissue analysis

Clinical
patient data

What is Medical Systems Biology? Integration of these levels in a way closer than ever before driven by technology to generate new points of intervention.

Program change:
Caroline Kampf is ill

11:15 - 12:45	**Session 1: Single Cells - Big Data** Chair: Peter Schirmacher, Peter Hamilton
11:15 - 12:00	Gerd Binnig (Definiens): "Tissue Phenomics and Big Data - the future of digital pathology?"
12:00 - 12:45	Michael Grunkin (Visiopharm): "Tissue Based Cancer Research and Diagnostics – The Devil is in the Data"
12:45 - 13:45	Lunch, Posters, Exhibition

The image processing battle

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Technology & Application

13:45 - 15:25	**Session 2: From Biomarkers to Patients** Chair: Niels Grabe, Gerd Binnig
13:45 - 14:15	Peter Hamilton (Queen's University Belfast / PathXL): "Picture Perfect: Digital pathology in stratified medicine and modern biomarker discovery"
14:15 - 14:35	Akiro Saito (NEC): "Prediction of HCC Recurrence by morphological measurement"
14:35 - 14:55	Gero Kramer (Vienna University / TissueGnostics): "Development and clinical testing of a novel user-independent image analysis software for quantitative analysis of immunostained cells in tissue biopsies"
14:55 - 15:25	Nicolas Wentzensen (NCI): "Whole slide scanning and automated image analysis for cervical cytology"
15:25 - 16:00	Coffee, Posters, Exhibition

Working Reliably

16:00 - 18:00	**Session 3: Changing Routine Pathology** Chair: Michiie Sakamoto (Keio University), Michael Grunkin
16:00 - 16:20	Peter Schirmacher (Heidelberg University): "Virtual microscopy and histopathological diagnostics applications and strategies"
16:20 - 16:50	Mogens Vyberg (Aalborg University): "New standards for data quality and diagnostic workflows in the pathology lab"
16:50 - 17:10	Michael Hummel (Charité Berlin): "NanoZoomer - a tool for FISH-applications?"
17:10 - 17:40	Paul Van Diest (University Utrecht): "Validation of digital diagnostics"
17:40 - 18:00	Janke Dittmer (Gilde Healthcare Partners): "Digital Pathology from an investor's perspective"

Counting the Tumor

9:00 - 10:00	**Session 4: Profiling the Tumor** Chair: Nicolas Wentzensen, Mogens Vyberg
9:00 - 9:20	Frederick Klauschen (Charité Berlin): "Computer-assisted breast cancer image analysis: Ki67 and beyond."
9:20 - 9:40	Richard Byers (University of Manchester): "Favourable diffuse prognostic pattern of FOXP3 +ve and CD69 +ve T-cells in follicular lymphoma demonstrated using hypothesised interaction distance (HID) automated prognostic feature identification"
9:40 - 10:00	Peter Caie (Edinburgh University): "Novel Prognostic Tools through Digital Pathology to Stratify High Risk Colorectal Cancer Patients"
10:00 - 10:30	Coffee, Posters, Exhibition

Linking Technology

10:30 - 12:30	**Session 5: Technology in Application** Chair: Paul van Diest, Yukako Yagi
10:30 - 11:00	Florian Markowetz (University of Cambridge): "Quantitative image analysis of cellular heterogeneity in breast tumors complements genomic profiling"
11:00 - 11:30	Daniel Racoceanu (National University of Singapore and Sorbonne Universities): "Whole slide analysis using a symbolic cognitive approach: Towards cognitive virtual microscopy in breast cancer histopathology."
11:30 - 11:50	Jeroen van der Laak (Radboud University Nijmegen): "Towards computer aided detection in Pathology"
11:50 - 12:10	Raphael Maree (Université de Liège): "A rich internet application for remote visualization, collaborative annotation, and automated analysis of whole slide images"
12:10 - 12:30	Steffen Härtel (Universidad de Chile): "From Microscopy, Imaging to Clinical Research: A Latin American Perspective"

3D Tissue Information

13:30 - 15:00	**Session 6: Exploring the Third Dimension** Chair: Daniel Racoceanu, Steffen Härtel
13:30 - 14:00	Yukako Yagi (Massachusetts General Hospital): "Challenges in Whole Slide Image Based 3D Imaging"
14:00 - 14:20	Niels Grabe (Heidelberg University): "Detection of the Mechanism of Wound Closure using WSI" (Kai Safferling ill)
14:20 - 14:40	Sven Lindemann (Merck Serono): "The use of whole slide imaging and digital histomorphometry for drug development in Osteoarthritis"
14:40 - 15:00	Katja Steiger (TU München): "Whole slide imaging in a comparative pathology setting with special emphasis on validation of multimodal molecular imaging"

The image processing battle

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