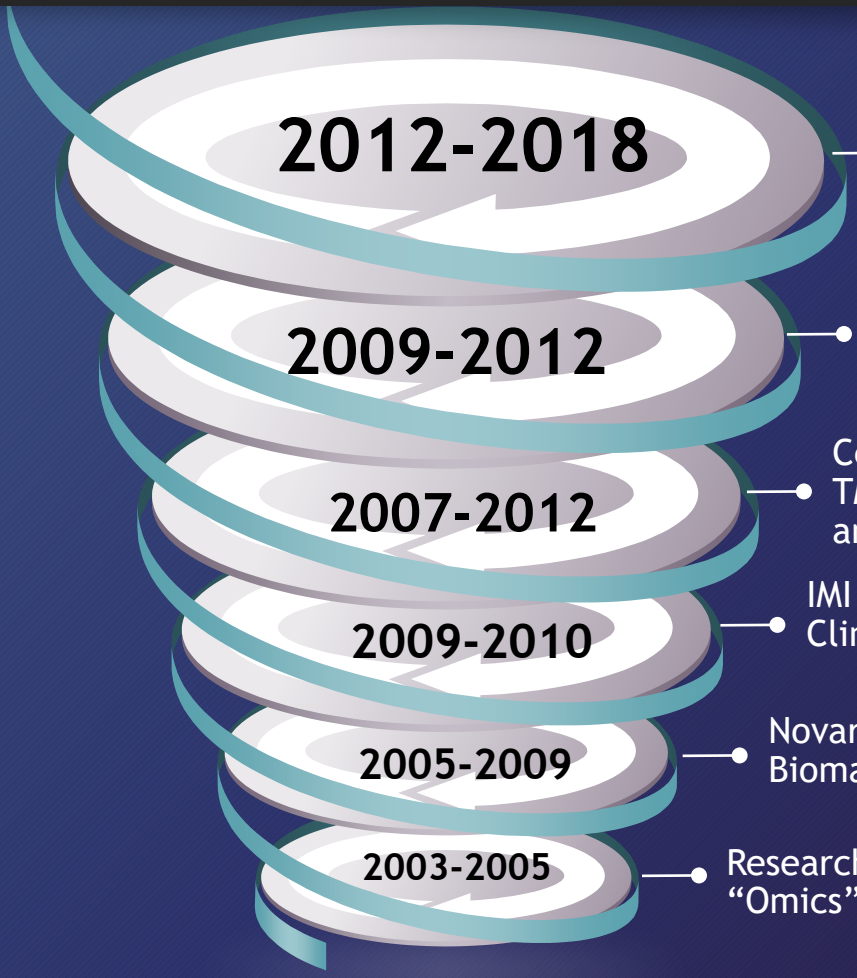
Making an Impact through Innovation, Implementation, Collaboration and Leadership

Key Professional Achievements
by Frank Dieterle, PhD

15 Years Experience in IVD and Drug Development



Near Patient Testing Unit:
Point of Care IVD Development, Manufacturing & Commercialization

MDx and CDx Unit:
Companion Diagnostics Development

Certican Drug GPT:
TM Representative for Drug Development and TDM IVD Assay Development

IMI SAFE-T Consortium Director:
Clinical Biomarker Qualification

Novartis – FDA Collaboration:
Biomarker Development & Regulatory Affairs

Research Scientist at Roche:
“Omics” and Big Data Analytics

1. Innovation
2. Collaboration
3. Implementation
4. Leadership

1. Innovation

Implementation of Advanced Data Analytics as Research Scientist at Roche (2003-2005)

Probabilistic Quotient Normalization as Robust Method to Account for Dilution of Complex Biological Mixtures. Application in ^{1}H NMR Metabonomics

F Dieterle, A Ross, G Schlotterbeck, H Senn - Analytical chemistry, 2006 - ACS Publications

For the analysis of the spectra of complex biofluids, preprocessing methods play a crucial role in rendering the subsequent data analyses more robust and accurate. Normalization is a preprocessing method, which accounts for different dilutions of samples by scaling the …

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- Implementation of advanced data analytics for -omics data with multivariate and AI technologies.
- Published innovative methods became industry standard

Leading the Novartis – FDA Collaborative Research and Development Agreement to establish regulatory pathways for biomarkers; 2016 implemented into law in the FD&C Act

Novartis plans joint research partnership with FDA
Novartis is planning to partner with the US Food and Drug Administration on three projects as part of the FDA's major effort called the Critical Path Initiative to modernize the medical product development process.

The first project will seek to identify and evaluate new manufacturing methods designed to assure quality. A second project will involve identifying a mechanism by which biomarkers can be validated for regulatory use in developing new drug therapies, while a third project will seek to find a regulatory pathway for the simultaneous development of a particular therapy and a diagnostic test kit that would enable the identification of patients who are most likely to benefit from the particular therapy.

2005

2016

21st Century Cures Act: Qualification of Drug Development Tools

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Under the 21st Century Cures Act,[1] enacted on December 13, 2016, a new section 507, Qualification of Drug Development Tools (DDT)[2], was added to the Federal Food, Drug, and Cosmetic Act. Building on the qualification program that FDA had voluntarily established and implemented for many years ("the legacy qualification program"), the 21st Century Cures Act formally established an updated, multi-step process for DDT qualification. Qualification of a DDT is for a specific context of use (COU), and the qualified DDT may be used for the COU by any person in drug or biologics development. The qualification process includes three submissions: the Letter of Intent (LOI), the Qualification Plan (QP), and the Full Qualification Package (FQP)[3]. Section 507 also includes transparency provisions that apply to requestors' submissions and FDA's formal written determinations in response to such submissions[4]. Consistent with the transparency provisions of section 507, FDA intends to publicly post the information contained in the table below Please note that the transparency provisions of section 507 (as outlined in Table 1) will apply only to submissions (LOIs, QP, and FQPs) sent to FDA after December 13, 2016 (when the 21st Century Cures Act was enacted). FDA's goal is to transition from the legacy qualification program process to the new section 507 DDT Qualification Process through a phased approach. We are developing a transition plan for existing projects, as well as section 507 submission documents (LOI, QP, FQP).

To engage with your respective **DDT** qualification program, see below.

Biomarker Qualification Program
Email: CDER-BiomarkerQualificationProgram@fda.hhs.gov

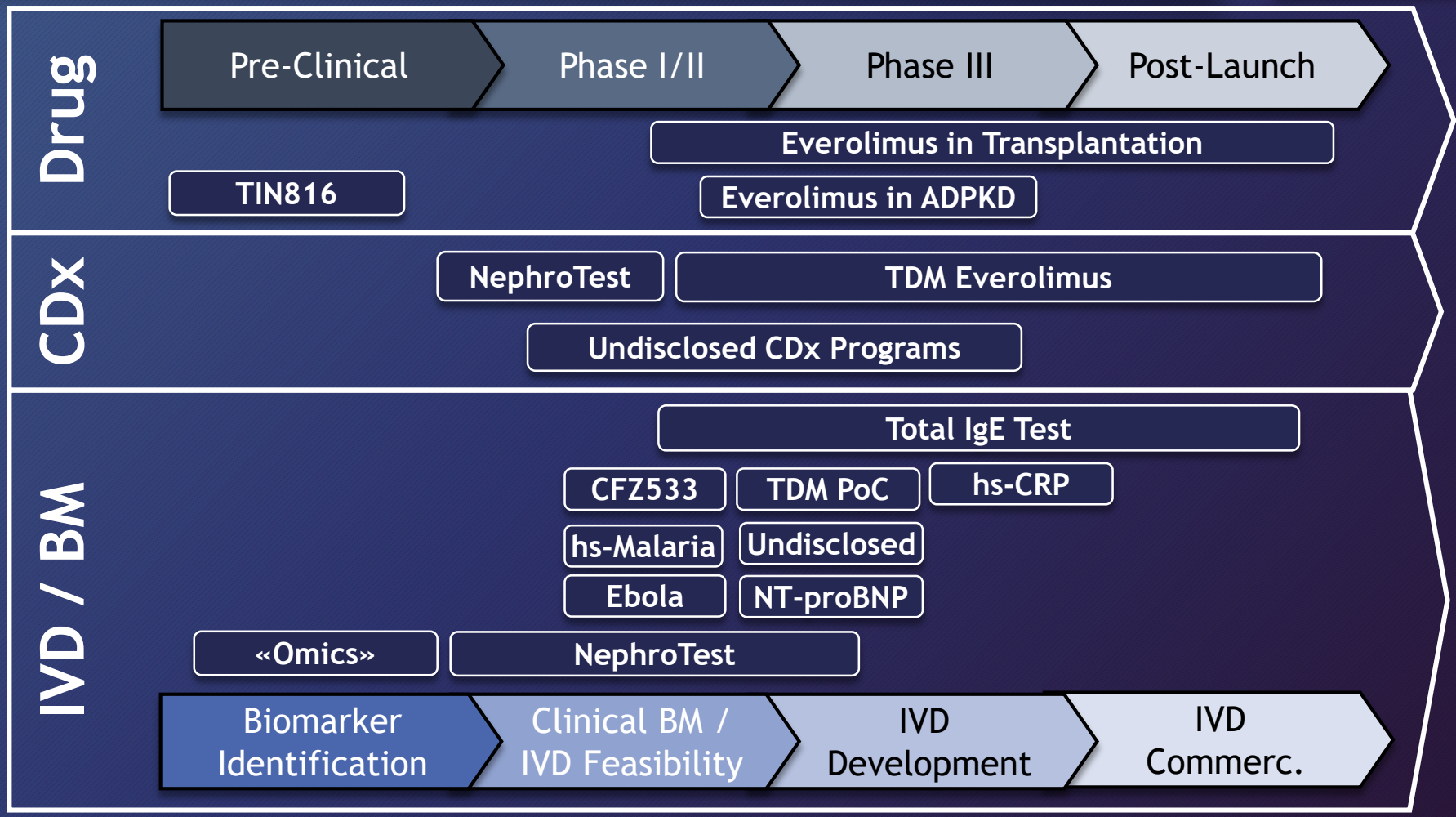
Leadership of the program for establishing new regulatory pathways for new innovative tools for drug development (2005-2009) resulted in the implementation of the proposals into US law 2016

Leading the Publication of Consortium and Biomarker Activities

Successfully led the science behind several kidney biomarkers and scientific activities of the PSTC Consortium later published in multiple articles in Nature Biotechnology

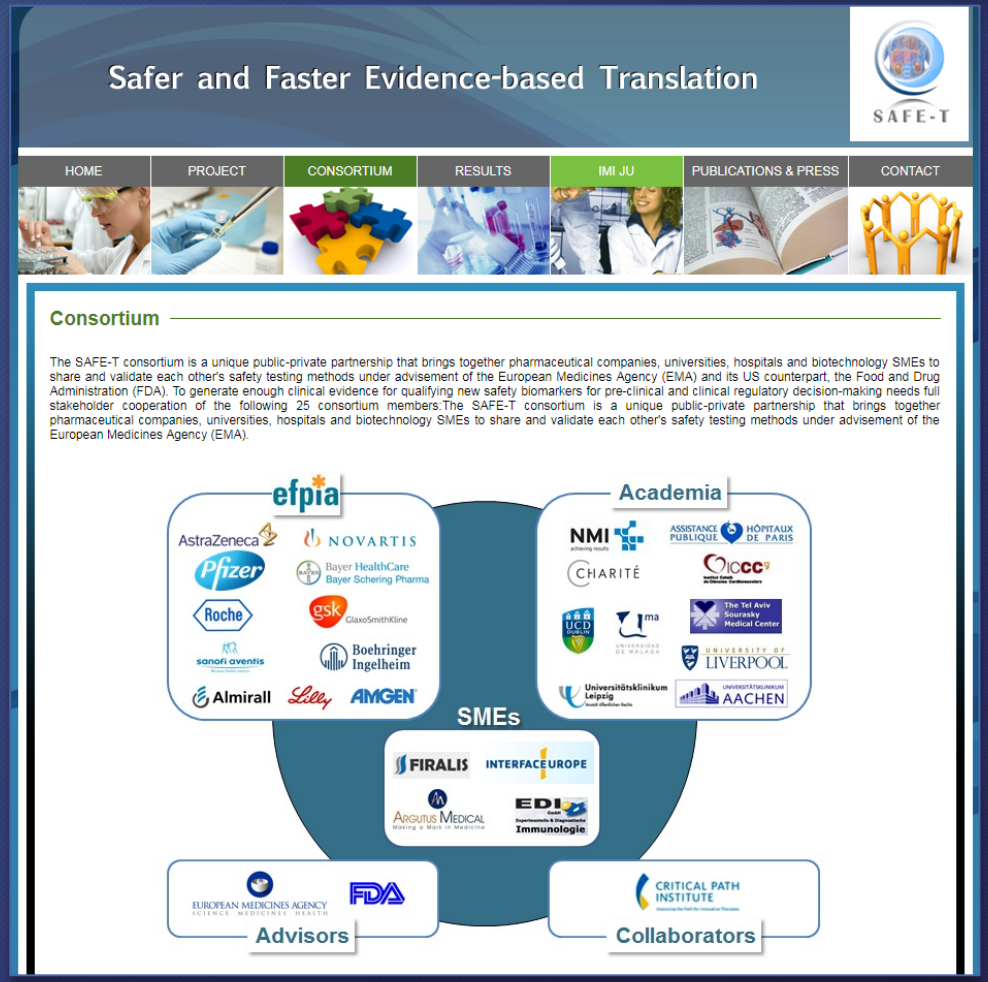
Nature Biotechnology Special Issue with 12 articles (5/2010)
http://www.nature.com/nbt/focus/pstc/index.html

Driver of a wide spectrum of projects across all Phases of Drug-, CDx-, IVD- and Biomarker-Development



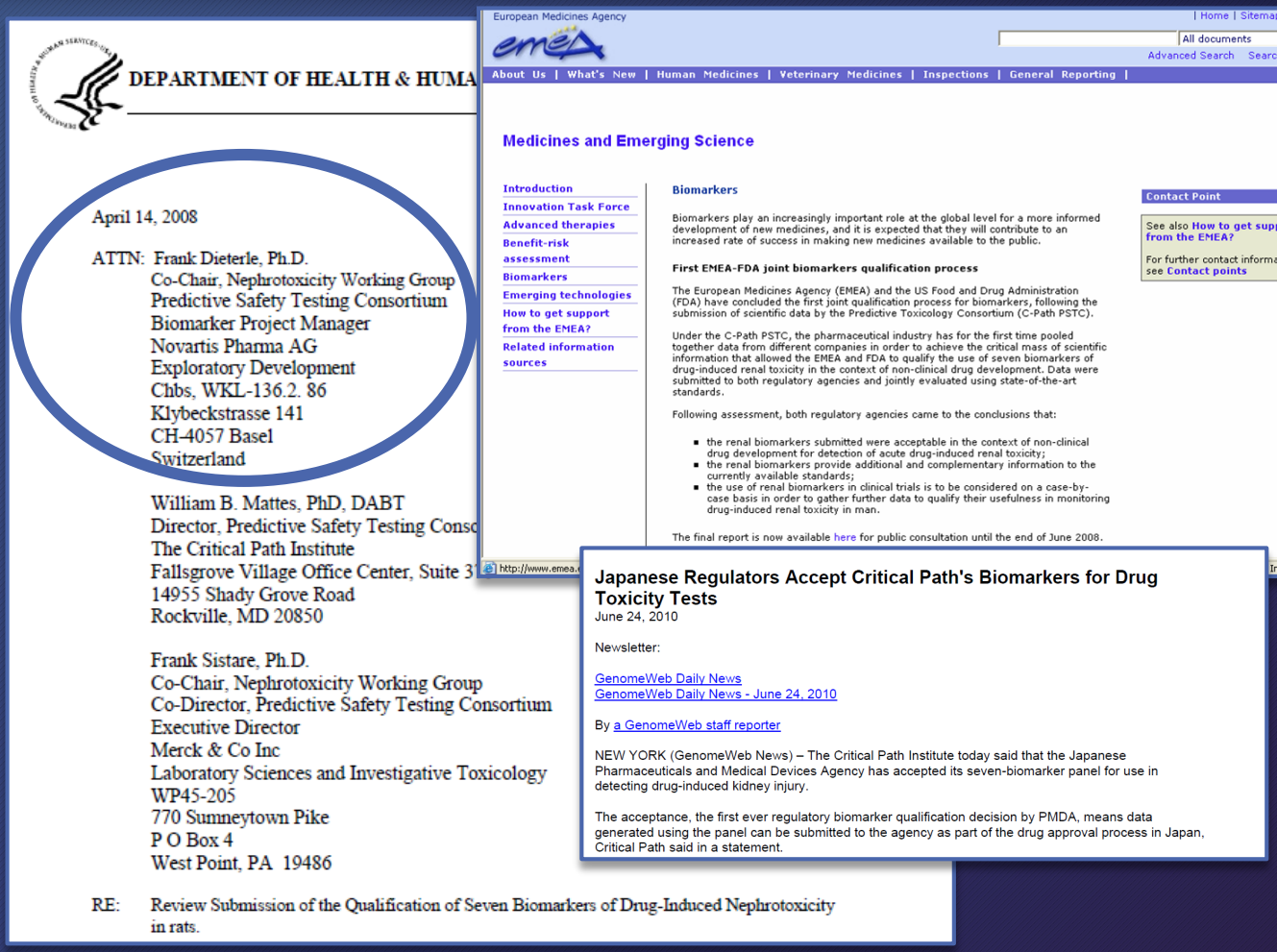
2. Collaboration

Founder of the IMI SAFE-T Consortium



- Co-founder and first Director of the first Consortium of the Innovative Medicines Initiative (IMI)
- Raised 36M € Budget
- Consortium obtained qualifcitation of several safety biomarkers as drug development tools (EMA and FDA)

First Successful Biomarker Qualification with EMA, FDA, PMDA (2005-2009)



DEPARTMENT OF HEALTH & HUMA

April 14, 2008

ATTN: Frank Dieterle, Ph.D.
Co-Chair, Nephrotoxicity Working Group
Predictive Safety Testing Consortium
Biomarker Project Manager
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Switzerland

William B. Mattes, PhD, DABT
Director, Predictive Safety Testing Consc
The Critical Path Institute
Fallsgrove Village Office Center, Suite 3
14955 Shady Grove Road
Rockville, MD 20850

Frank Sistare, Ph.D.
Co-Chair, Nephrotoxicity Working Group
Co-Director, Predictive Safety Testing Consortium
Executive Director
Merck & Co Inc
Laboratory Sciences and Investigative Toxicology
WP45-205
770 Sumneytown Pike
P O Box 4
West Point, PA 19486

RE: Review Submission of the Qualification of Seven Biomarkers of Drug-Induced Nephrotoxicity in rats.

European Medicines Agency

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Medicines and Emerging Science

- Introduction
- Innovation Task Force
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- Benefit-risk assessment
- Biomarkers
- Emerging technologies
- How to get support from the EMEA?
- Related information sources

Biomarkers

Biomarkers play an increasingly important role at the global level for a more informed development of new medicines, and it is expected that they will contribute to an increased rate of success in making new medicines available to the public.

First EMEA-FDA joint biomarkers qualification process

The European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA) have concluded the first joint qualification process for biomarkers, following the submission of scientific data by the Predictive Toxicology Consortium (C-Path PSTC).

Under the C-Path PSTC, the pharmaceutical industry has for the first time pooled together data from different companies in order to achieve the critical mass of scientific information that allowed the EMEA and FDA to qualify the use of seven biomarkers of drug-induced renal toxicity in the context of non-clinical drug development. Data were submitted to both regulatory agencies and jointly evaluated using state-of-the-art standards.

Following assessment, both regulatory agencies came to the conclusions that:

- the renal biomarkers submitted were acceptable in the context of non-clinical drug development for detection of acute drug-induced renal toxicity;
- the renal biomarkers provide additional and complementary information to the currently available standards;
- the use of renal biomarkers in clinical trials is to be considered on a case-by-case basis in order to gather further data to qualify their usefulness in monitoring drug-induced renal toxicity in man.

The final report is now available here for public consultation until the end of June 2008.

Contact Point

See also How to get support from the EMEA?

For further contact information see Contact points

http://www.emea.

Internet

Japanese Regulators Accept Critical Path's Biomarkers for Drug Toxicity Tests

June 24, 2010

Newsletter:

GenomeWeb Daily News
GenomeWeb Daily News - June 24, 2010

By a GenomeWeb staff reporter

NEW YORK (GenomeWeb News) – The Critical Path Institute today said that the Japanese Pharmaceuticals and Medical Devices Agency has accepted its seven-biomarker panel for use in detecting drug-induced kidney injury.

The acceptance, the first ever regulatory biomarker qualification decision by PMDA, means data generated using the panel can be submitted to the agency as part of the drug approval process in Japan, Critical Path said in a statement.

Drove the C-Path PSTC Consortium activities leading to the first-ever approval of biomarkers by FDA, EMA and PMDA

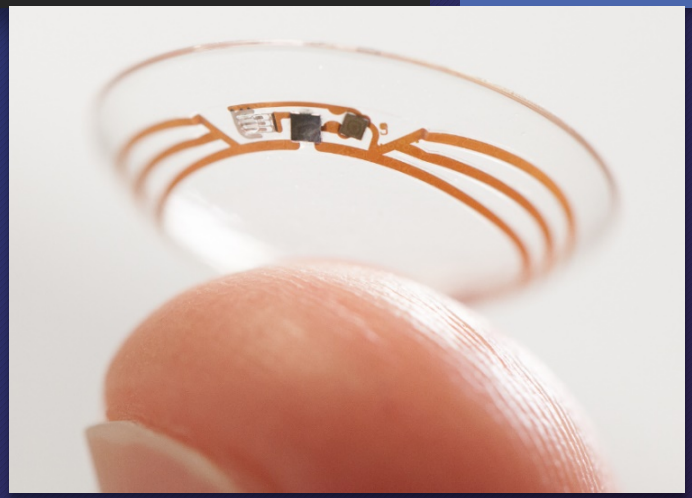
Several Successful Due Diligences and Deals, e.g Google – Alcon Deal

Novartis to license Google "smart lens" technology

Jul 15, 2014

- *Innovative technology offers potential to transform eye care and further enhance Alcon's leadership in contact lenses and intraocular lenses*
- *Agreement is a first step for Novartis to evolve technology to manage human diseases and conditions*

Basel, Switzerland, July 15, 2014 – Novartis announced that its eye care division Alcon has entered into an agreement with a division of Google Inc. to in-license its "smart lens" technology for all ocular medical uses. The agreement with Google[x], a team within Google that is devoted to finding new solutions to big global problems, provides Alcon with the opportunity to develop and commercialize Google's "smart lens" technology with the potential to transform eye care and further enhance Alcon's pipeline and global leadership in contact lenses and intraocular lenses. The transaction remains subject to anti-trust approvals.



Successful due diligences led to the in-licensing of multiple projects in the area of IVD and personalized medicine, e.g. the Google – Alcon (Novartis) Deal

Collaboration with the Bill and Melinda Gates Foundation

Initiated and drove a collaboration with BMGF resulting in successful development of point of care tests for Ebola and hs-Malaria (RUO, successfully evaluated in the Marburg BSL-4 labs)

Picture taken on November 10, 2014

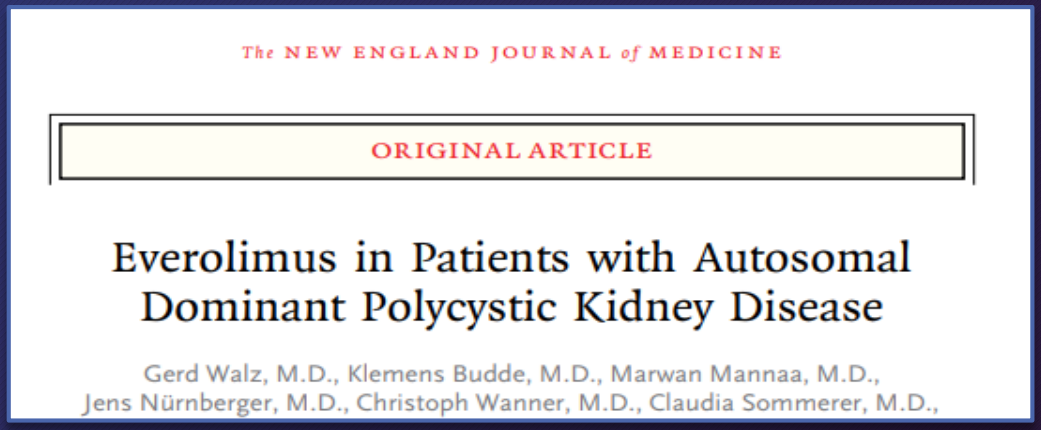
3. Implementation

Core Member of Novartis Drug Teams in Transplantation and Nephrology with Several Phase II-IV Studies and Approvals

Novartis drug Zortress® is first in over a decade approved by FDA to prevent organ rejection in adult liver transplant patients

- Zortress is the first mTOR inhibitor approved to prevent organ rejection in adult liver transplant patients in the US, where it is already approved for kidney transplantation
- Approval based on positive outcomes from largest liver transplant study ever, comparing Zortress plus reduced-exposure tacrolimus to standard tacrolimus1
- Under trade name Certican®, the drug was approved by European Health Authorities for use in adult liver transplant patients in the fourth quarter of 2012

Drove Personalized Medicine Aspects (e.g. TDM assays) leading to the approval of the Drug Certican™/Zortress™ in several indications



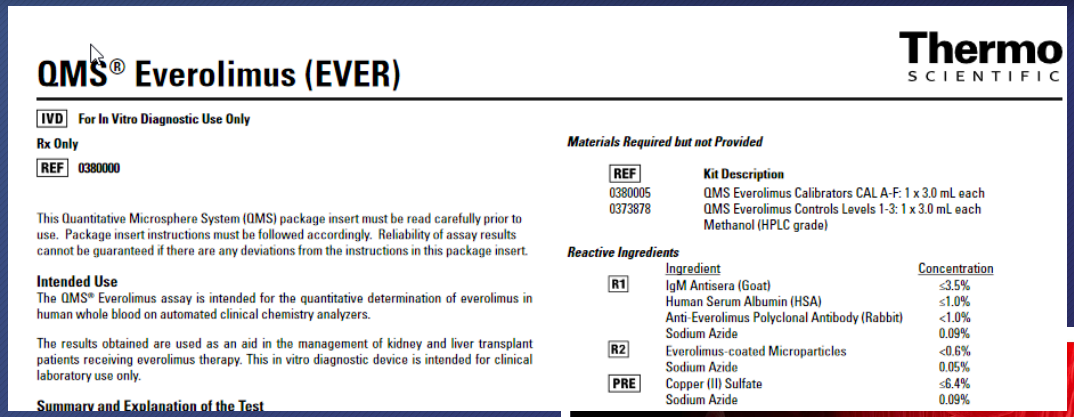
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Everolimus in Patients with Autosomal Dominant Polycystic Kidney Disease

Gerd Walz, M.D., Klemens Budde, M.D., Marwan Mannaa, M.D., Jens Nürnberger, M.D., Christoph Wanner, M.D., Claudia Sommerer, M.D.,

Core Member of the Novartis MDx and CDx programs to develop Companion Diagnostics Tests to support Novartis drugs



QMS® Everolimus (EVER)

Thermo SCIENTIFIC

IVD For In Vitro Diagnostic Use Only

Rx Only

REF 0380000

This Quantitative Microsphere System (QMS) package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Intended Use

The QMS® Everolimus assay is intended for the quantitative determination of everolimus in human whole blood on automated clinical chemistry analyzers.

The results obtained are used as an aid in the management of kidney and liver transplant patients receiving everolimus therapy. This in vitro diagnostic device is intended for clinical laboratory use only.

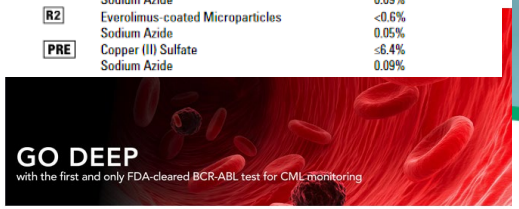
Summary and Explanation of the Test

Materials Required but not Provided

REF	Kit Description
0380005	QMS Everolimus Calibrators CAL A-F: 1 x 3.0 mL each
0373878	QMS Everolimus Controls Levels 1-3: 1 x 3.0 mL each
	Methanol (HPLC grade)

Reactive Ingredients

	Ingredient	Concentration
R1	IgM Antisera (Goat)	≤3.5%
	Human Serum Albumin (HSA)	≤1.0%
	Anti-Everolimus Polyclonal Antibody (Rabbit)	<1.0%
	Sodium Azide	0.09%
R2	Everolimus-coated Microparticles	<0.6%
	Sodium Azide	0.05%
PRE	Copper (II) Sulfate	≤6.4%
	Sodium Azide	0.09%



Sensitivity that takes molecular response monitoring to a whole new level

Assessing complete molecular response requires the highes possible assay sensitivity. The FDA-cleared QuantideX® qPC BCR-ABL IS Kit takes chronic myeloid leukemia (CML) monitoring to a new level of sensitivity at MR4.7 (0.002% IS With this unprecedented level of sensitivity coupled to a simple-to-run, singlicate test, you can now reliably and reproducibly monitor much deeper molecular response.

Development of Companion Diagnostics and Complementary IVD Tests with IVD partners to Support the Novartis Drug Portfolio

Launch of the first IVD Test and IVD Platform developed by Novartis Pharma

Successful implementation of business proposal from ideation to development and launch of the Niji™ Point of Care Platform and Total IgE test to support the Novartis drug "Xolair™".
Development of hardware, firmware / software and reagents / cartridges under design control.

New Novartis point of care Niji™ System may provide earlier diagnosis of severe allergic asthma and faster treatment decisions

- *Nijiᵀᴹ System, Total IgE Test delivers results rapidly, allowing for quick in-office diagnosis of IgE-mediated allergic disorders and faster treatment decisions*
- *Point of care in office diagnostics may accelerate treatment decisions that could lead to improved patient care and outcomes*
- *Niji System, using only one to two droplets of finger stick blood, provides flexible and easy to use point of care platform with the potential to be used across various disease areas*

Basel, September 9, 2016 – Novartis announced today the introduction of a novel in office point of care diagnostic tool – the Nijiᵀᴹ System and Total IgE Test. This first test delivers quantitative total IgE (Immunoglobulin E) levels in about 12 minutes using only one to two droplets of finger stick blood, allowing for quick in-office diagnosis of IgE-mediated allergic disorders in conjunction with other clinical findings.

MEDIA

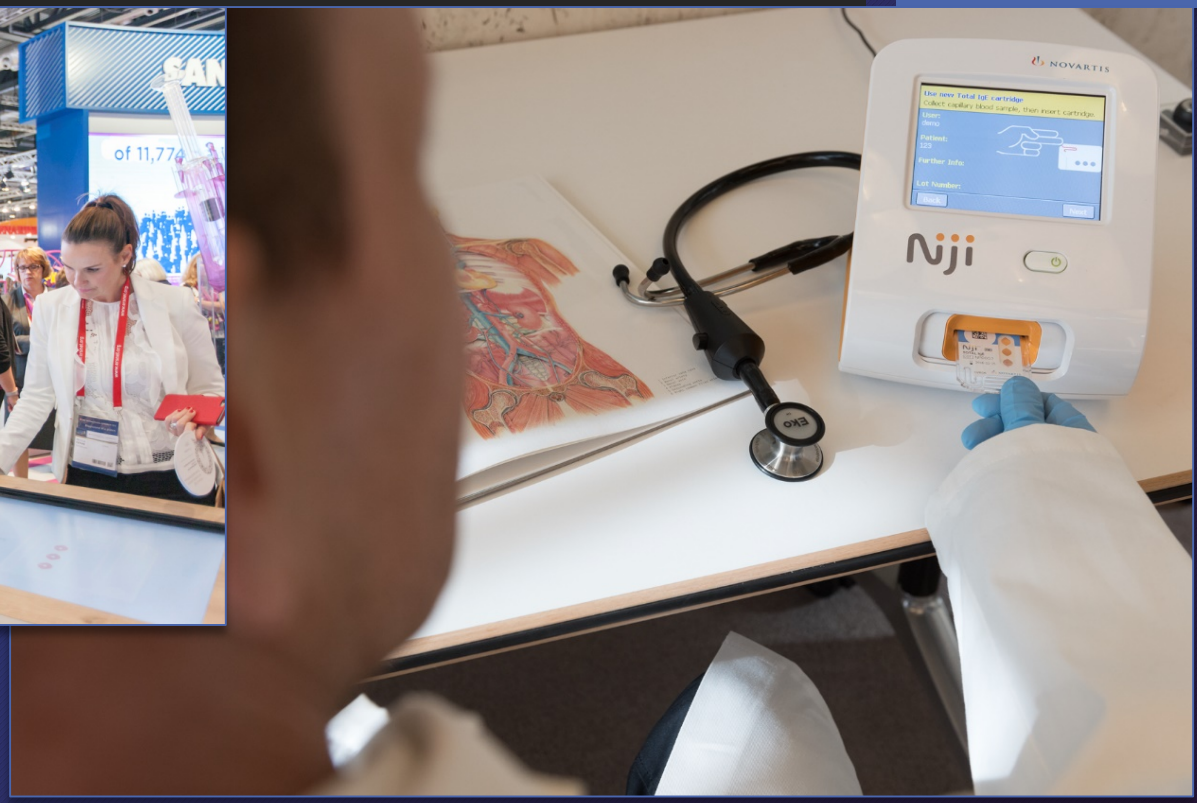
PHOTO:
Niji System analyzer

Download

PHOTO:

Full Press Release at:
https://www.novartis.com/news/media-releases/new-novartis-point-care-nijitm-system-may-provide-earlier-diagnosis-severe

Rolling out the Niji Point of Care IVD Platform and First IVD Test (Total IgE)



Pictures taken at the ERS yearly meeting in London, September 5,2016

Initiated and executed the development of multiple Point of Care IVD programs and launch of the first IVD test in several countries

4. Leadership

Acquisition of Biotech Company Vivacta and Integration into Novartis as NPT (Near Patient Testing)

Vivacta Sold to Major Pharmaceutical Company for USD 90 Million

Company Vivacta, Novartis
Tags Acquisition
Date December 17, 2012

HBM Healthcare Investments announced today that Vivacta Limited, a privately held point-of-care diagnostic company in the portfolio, has been acquired by Novartis (SIX: NOVN; NYSE: NVS) for a total consideration of USD 90 million, subject to post-closing adjustments. This acquisition follows a successful collaborative relationship to assess Vivacta 's piezofilm technology in the new area of near-patient drug monitoring.

HBM Healthcare Investments invested a total of GBP 4.1 million in Vivacta since November 2007 and owns 17 percent of the company. The transaction increases the net asset value (NAV) per share by CHF 0.79 (+1.3%).

Created the business case for the acquisition and obtained support and funding from Novartis Leadership

Leading the Transforming of the Small Biotech into an ISO-13485 Certified Novartis Site in Kent for Development, Manufacturing and Commercialization of IVD Tests

Established all line-functions and processes to research, develop, manufacture (GMP) and commercialize IVD test with full ISO-13485 Certification starting with a 35-associates biotech company.

Pictures of the Novartis NPT facilities in Sittingborne, Kent, UK.
Top picture: Development (left) and manufacturing facilities (right)
Bottom picture: Research facilities (right) and supporting functions (middle)

Leading the Transformation of NPT after Strategic Decision of Novartis to Exit IVD Business: Decommissioning, Transfer, Out-licensing, Closure

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Home > Sittingbourne > News > Article

Novartis Pharmaceuticals announces it intends to close branch at Kent Science Park, Sittingbourne

LIVE NEWS

SIGN ME UP FOR NEWS ALERTS

By Lewis Dyson ldyson@thekmgroup.co.uk

Read all comments | 5

Published: 16:00, 30 November 2017 | **Updated:** 16:00, 30 November 2017

More than 70 employees have been told their jobs are under threat after a pharmaceutical company announced it intends to close its Sittingbourne branch.

Workers at Novartis Pharmaceuticals on the Kent Science Park, in Broadoak Road, were called into a meeting today where news of the closure was broken to them.

The site is a Near Patient Testing (NPT) unit that developed the Niji point of care diagnostic device used by medical professionals to diagnose allergic disorders and make treatment decisions.

Leading the closure, decommissioning, transfer and out-licensing of NPT technologies and the Novartis Kent site

“The horizon leans forward, offering you space to place new steps of change”

Maya Angelou

Picture taken above Zermatt, Switzerland (April 14, 2016 by Frank Dieterle)

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