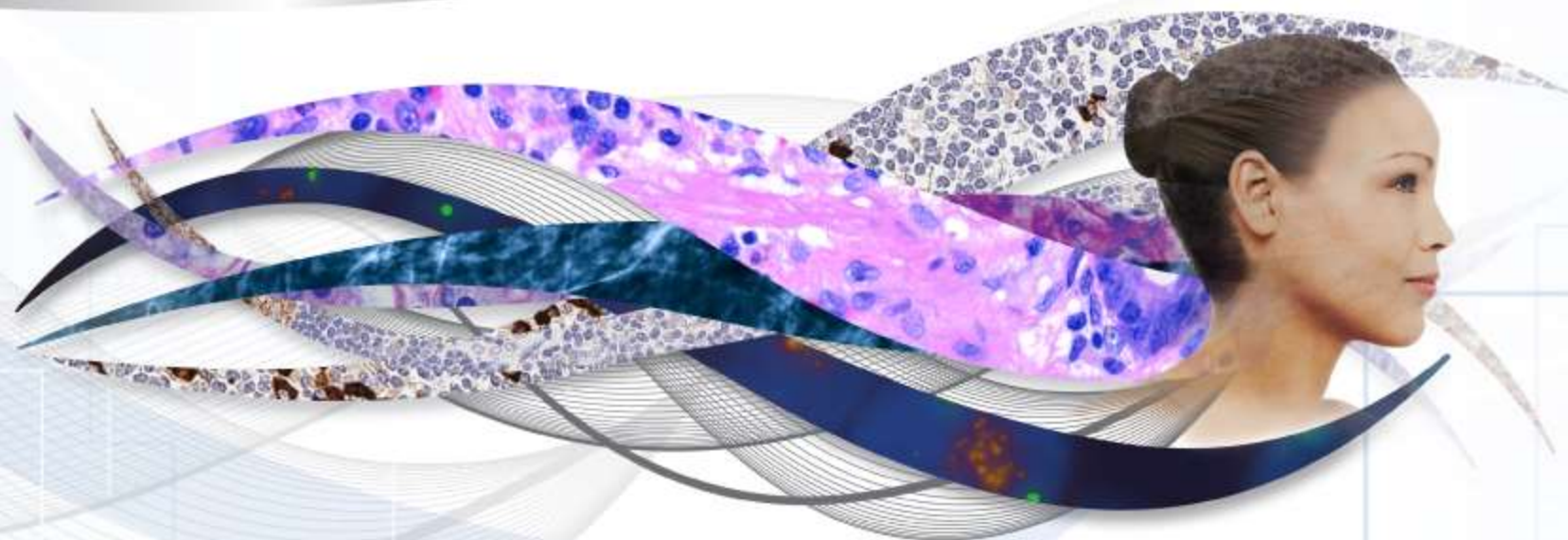


LEICA BIOSYSTEMS



Advancing Cancer Diagnostics
Improving Lives

VISION 24



Leica
BIOSYSTEMS

Leica Biosystems Proprietary Information

LEICA BIOSYSTEMS

Leica Newcastle
- our collaborations with the Molecular
Node

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Diagnostics North East April 2019



Agenda

1. Who are we and where are we based
2. What do we do and why we do it – VISION 24
3. Examples of collaborations with Node
 - Biobank
 - Tissue TMAs
 - Competitor staining and Pathology expertise
 - Clinical Evidence generation
 - Talent
4. Where next ?



Who We Are and Where Are We Based

- Leica Biosystems is a global leader in workflow solutions and automation for Cancer Diagnostics. We supply all testing reagents required for the detection of biomarkers and DNA and RNA sequences used to provide specific cancer identification and to aid identification of effective therapies
- Leica Newcastle has **180 employees in Newcastle** and **30 employees in Amsterdam**
- Annual turnover of \$200 million , ~ 45% of business is in the USA.
- Newcastle is a joint manufacturing and development site – over 400 abs are grown at the site and dispatched for Next day receipt for UK customers.
- Our history takes us back a full circle to a NCL spin out called Novocastra in 1998
- We combine the power of two acquired companies with strong heritage in their field.
 - **Novocastra** (based in Newcastle, UK) was acquired just over 10 years ago (via acquisition of Vision Biosystems) and has over 25 years experience of supplying Immunohistochemistry products.
 - **Kreatech** (based in Amsterdam, Netherlands) as acquired about 4 years ago and has over 20 years experience of supplying fluorescent reagents (FISH probes) identifying DNA se



Leica Biosystems is part of Danaher

Water Quality



Dental



Life Sciences



Diagnostics



Product Identification



- Hach
- ChemTreat
- McCrometer
- Karvo Keer
- Nobel Bio C
- Ormco
- Leica Micro
- Pall
- Mol Dev
- McCrometer
- Leica Bio
- Beckman
- Radiometer
- Cepheid
- LINX
- Video jet
- ESKO

Collectively, Danaher own over 40 Op-Cos, split into 5 strategic groupings all focused on Helping Realizing Life's potential

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What do we do and why do we do it?



VISION 24

To enable clinicians to efficiently provide patients a highly confident diagnosis within 24 hours of biopsy.



THE COMBINATION OF THESE THREE PILLARS WILL ENABLE LEICA BIOSYSTEMS TO LEAD OUR CUSTOMERS TO EXPERIENCE BREAKTHROUGH ADVANCES IN DIAGNOSTIC CONFIDENCE AND TURNAROUND TIME.



Examples of recent collaboration

1. CEPA Biobank
2. Tissue TMAs
3. Competitor staining and Pathology expertise
4. Clinical Evidence generation
5. Talent

CEPA BIOBANK - How is human tissue used at Leica?



- **Quality Control** ~ 350 blocks /year
- **Shelf life generation** ~ 100 blocks per year.
- **Research and Development** ~ 500 blocks per year

Leica purchase ~ 2000 human tissue blocks a year – most from US – no guarantee of quality and no local economy reinvestment

CEPA BIOBANK – timeline of events

- 2015

- Introductions made between Leica and the Trust regarding potential use for left over tissue as Quality Control material

- 2016

- Leica joined the Trust and Prof Phil Sloan and Sheila Graham at TWO patient participation workshops, one with adults and with children. Both suggested that public opinion was favourable regarding use of tissue by a 'Cancer Diagnostics' company
- Leica received patients and patient relatives on site for a tour – 'the Life of a tissue block'

- 2017

- March - The Trust's ethics application for a BioBank is approved - comments from the chair, 'an excellent application...very good example of how researchers can involve service users and patient groups with the design of an application
- November - The CEPA Biobank collected its first sample and is now open for business with industrial and academic partners

- 2019

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- April, Leica purchases tonsil blocks – currently under evaluation.....

The first blocks arrive, hand delivered!



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Tissue Micro Array manufacture

TMA Manufacture and sectioning

- Node supported Leica BioSystems with manufacture of bespoke Tissue Micro Arrays.
- The automated instrument used allowed a core size and sample quantity exceeding the capability of our site (or would have been very technically burdensome to complete internally).
- Node also took on the subsequent microtomy that protected Leica BioSystems resource – particularly helpful due to the slide quantity and TAT required.

Competitor testing

Breast cancer IHC screening and specialist pathologist expertise

- Leica BioSystems utilised NODE contractual IHC services to conduct screening of a large clinical tissue cohort supporting a high value development project.
- For this body of work the relationship with Node enabled access not only to a competitor's platform (and associated reagents), but also a specialised technical team that could accommodate a significantly compressed TAT.
- Dr Howitt provided invaluable clinical Voice of Customer during development of a breast IHC assay. The guidance offered contributed directly to product reformulation (Ab concentration) and protocol selection, resulting in final specifications used today .

Clinical Evidence generation

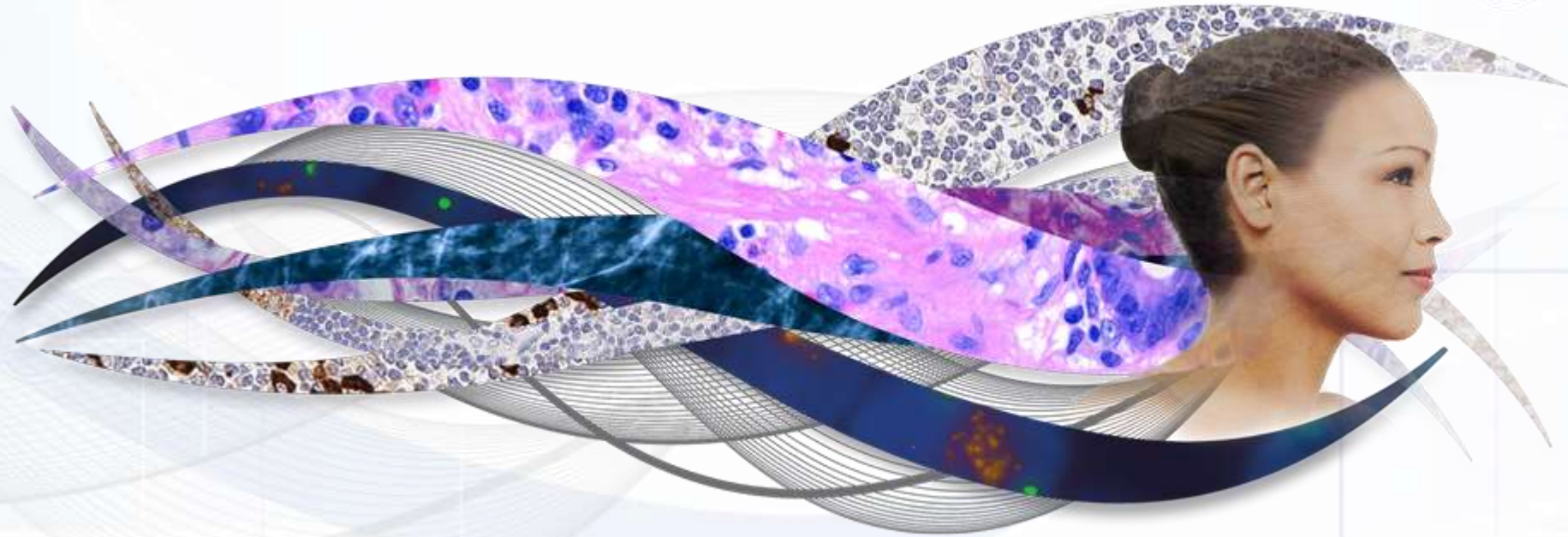
P16 staining / cohort access

- Cellular Pathology will be contracted to conduct a Clinical Research study, supporting a key Leica BioSystems marketing initiative.
- This collaboration allows access to a fully characterised clinical trial cohort, competitor staining instrument and reagents and direct point of contact within Research Ethics Committee etc, there by enabling generation of data that will be available in support of launch activities.

Talent

1. The Molecular Node have kindly offered Leica a bursary for an associate to complete a 3 year MSc in Molecular Pathology – this is a fanatic development opportunity and we are really grateful to the Node for considering us.
2. Currently we have two students completing their sandwich years with us – great additions to our team and a super way of gaining hands-on, industry experience from one of the leading players in cancer diagnostics.
3. Continued success....we have a strong track record of attending careers fairs, retaining students and recruiting graduates.
4. Fantastic talent pool.....please check out our website for current vacancies
😊

Thank you and any questions



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