

Introduction to UCB and Statistical Programming

UNC STOR 320: Intro to Data Science

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Inspired by patients.
Driven by science.



Agenda

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2. UCB History and Growth
3. UCB Values – Our Patient Value Principles
4. SSI Overview
5. SSI Locations
6. SSI Groups and People
7. SSI Roles
8. Studies & Stakeholders
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UCB – A Global Biopharma Company

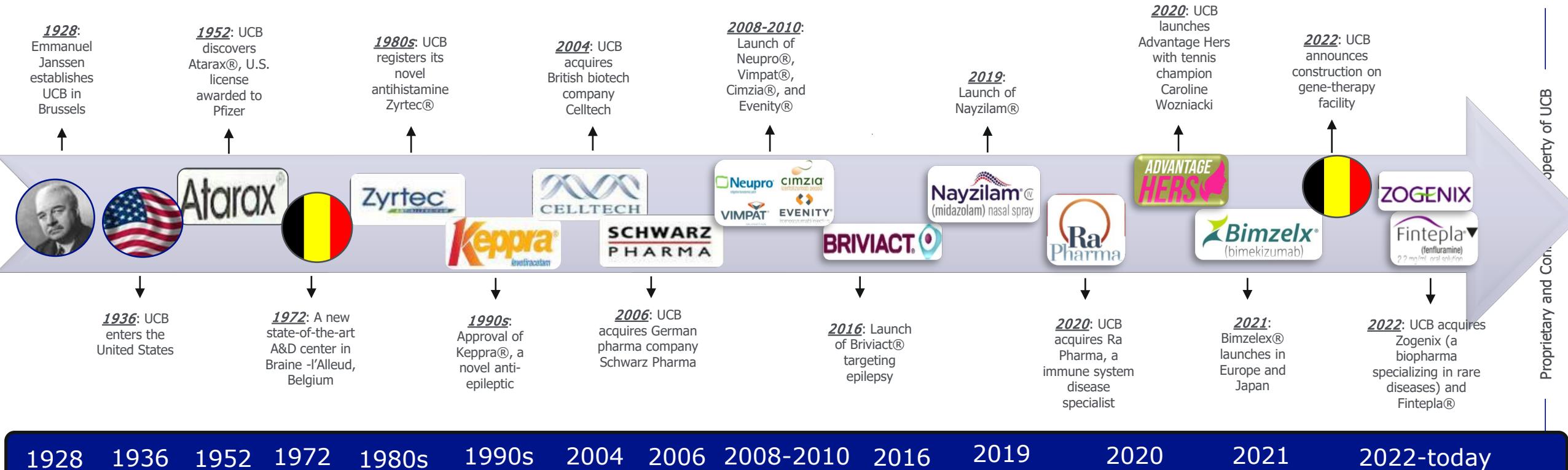
At UCB, we believe that everyone deserves to live the best life that they can. That's why – as a global biopharmaceutical leader - we're focused on creating valuable solutions that make improvements to the lives of people living with neurological and autoimmune conditions now and into the future.

This success is powered by the approximately 8,700 people – from our headquarters in Belgium and across nearly 40 countries worldwide. Our people have lived our purpose each day since 1928, making critical investments in biopharmaceutical research and leading innovations that strive to achieve a meaningful impact on the lives of those we serve.

UCB Statistical Sciences & Innovation



The Growth and Development of UCB BioPharma



Chemical Group

Primary Care Pharma

Speciality Bio-Pharma

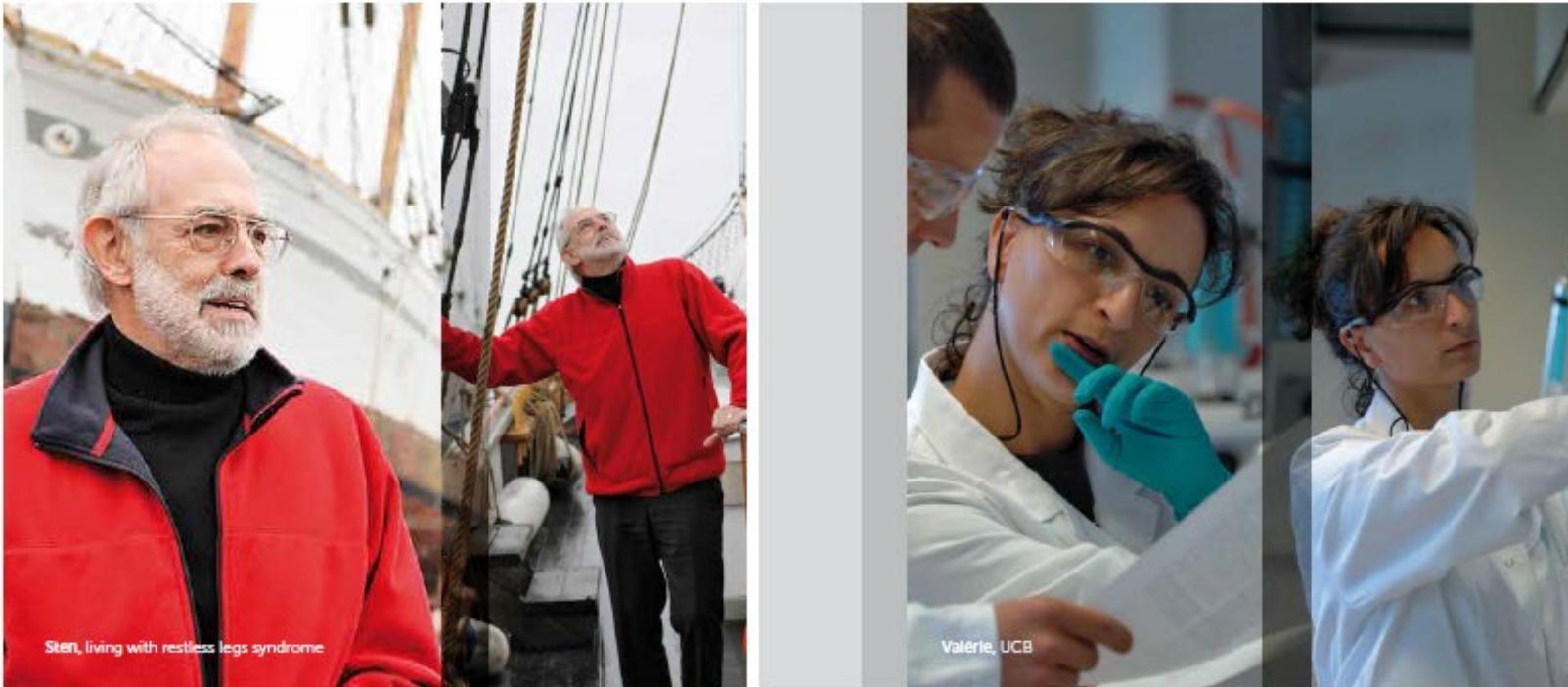
Passion for Performance

People with severe diseases inspire us to make a meaningful difference to as many lives as possible

I demand the best of myself and others. I execute flawlessly and strive for continuous improvement

Our values

What we share



Innovation

People living with severe diseases rely on us to develop new creative solutions that will have a positive impact on their lives

I understand patient needs better than the competition and translate this insight into distinctive solutions

Entrepreneurship

Entrepreneurs think big and constantly focus on creating superior customer value

I relentlessly take on selected initiatives with energy, resilience and a 'can do' attitude

Integrity

Overarching principle by which we operate, engage and interact with customers and other stakeholders, as well as one another

I constantly act in a transparent, authentic and ethical way

Embracing Differences

Diversity of thoughts and an inclusive approach are cornerstones of success

I actively listen, seek and embrace different perspectives

Accountability

Holding ourselves and each other accountable delivers superior & sustainable value to patients

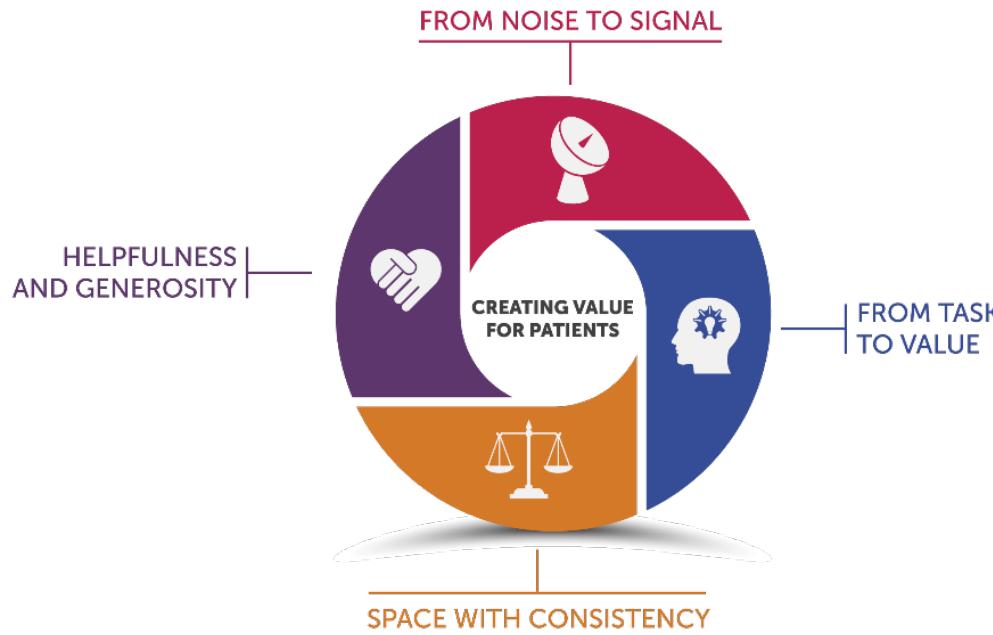
I'm empowered and act as if UCB's success as a whole depends on my contribution

Care

Caring for people with severe diseases, customers and colleagues is at the heart of what we do and makes us better

I act with empathy, openness, generosity and helpfulness - and I treat others as I would like to be treated

The Patient Value Principles



From Noise to Signal

Develop a **deeper understanding** of the patient's reality and the ecosystem of care

Derive actionable **solutions based on true insights** rather than assumptions/opinions



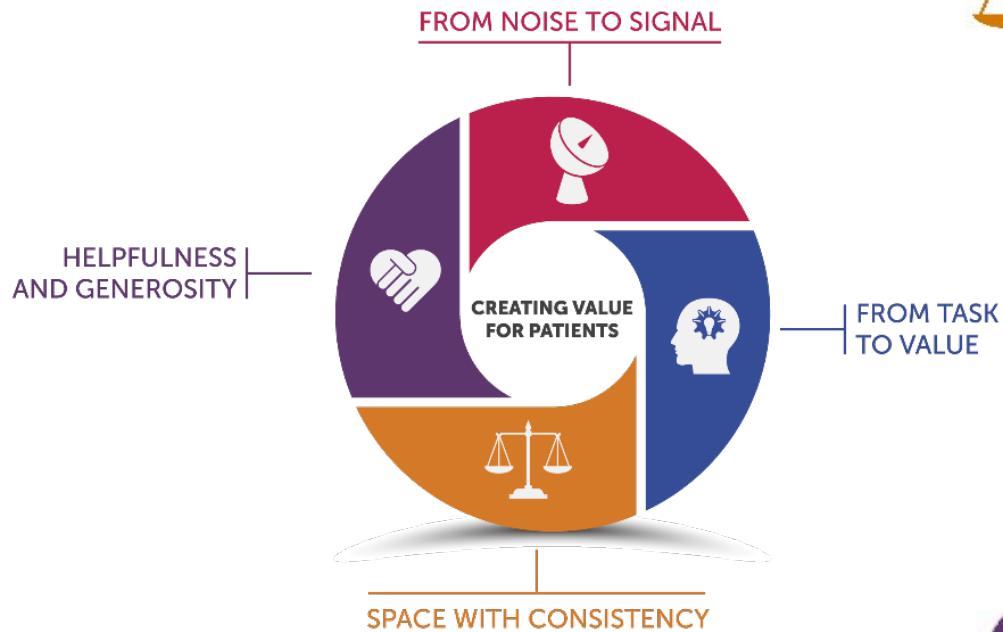
From Task to Value

Take **initiative** and work towards **creating patient value**, rather than completing a task

Challenge self & others on value creation before committing to action

Take courageous decisions and **balanced risks** to create value for patients & UCB

The Patient Value Principles



Space with Consistency

Consider **successes & failures** as a means **to learn and improve**



Proactively **share knowledge** with others

Provide Space: allow others freedom to act and to provide alternative solutions

Occupy Space with consistency: take accountability for trying new ideas/approaches that are aligned with our purpose, strategy and values

Align efforts toward a **common purpose** to ensure maximum **impact for patients**

Helpfulness and Generosity

Invest in **building trustful relationships** with in- & external stakeholders

Generously offer help and resources to others in the interest of the business

Encourage and **leverage diversity** to improve outcomes

Use **healthy debate** to encourage diversity of thinking and improve outcomes

Statistical Sciences & Innovation (SSI) Overview

Statistical Excellence

The SSI group drives statistical excellence and innovation from pre-clinical through to Clinical development, registration and beyond.

Learning and Innovation

The SSI group supports studies across all phases in a compound centric fashion ensuring the expertise, learning and innovation follow each compound across all stages of clinical development.

Optimum Efficiency

The SSI group has an aim to ensure efficiency in development programs and optimising the insight from data using the latest statistical methods.

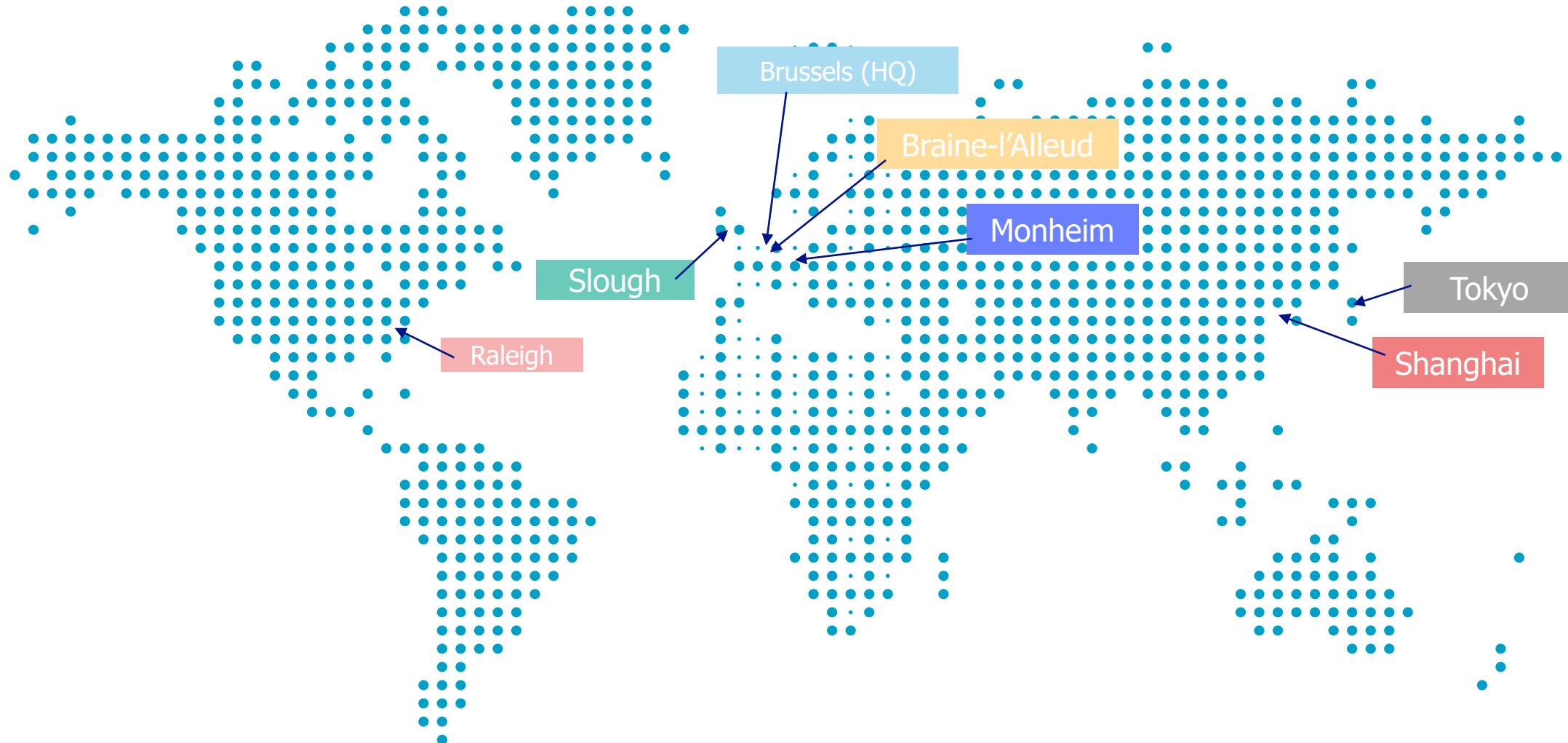
Patient Value

Across SSI, the goal is to be centre of excellence in statistical sciences, strengthening our industry leading talent and maximisation of patient value in everything we do.



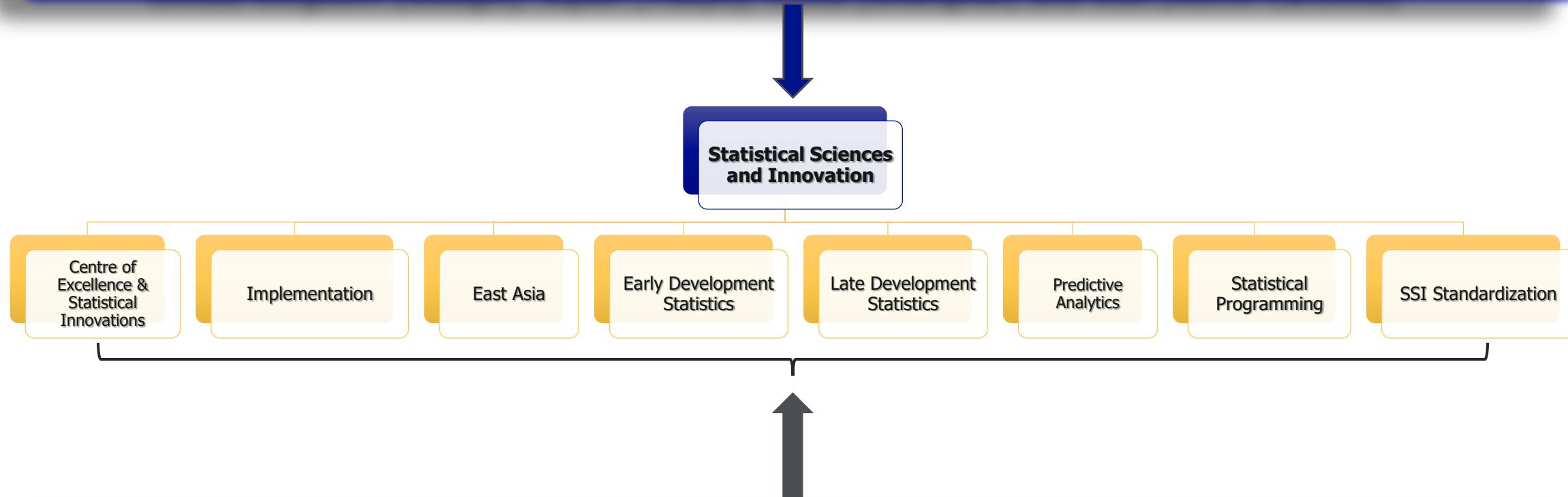
SSI Locations

A diverse team situated around the world.



SSI: Locations Groups and People

SSI global locations include: Belgium (Braine-l'Alleud/Anderlecht/Brussels), Germany (Monheim), United Kingdom (Slough), Japan (Tokyo), China (Shanghai) and USA (North Carolina)



SSI teams are made up of: UCB Staff, Contractors and Functional Service Providers (FSP: Veramed, Cytel, Covance)

SSI: Locations, Groups and People (cont'd)

SSI Implementation:

- focuses on actions and non-project goals to deliver on activities in a methodical and managed approach utilizing key project management skills

Centre of Excellence & Statistical Innovation (CESI):

- promotes, introduces and drives Statistical Innovation at all levels in UCB

Early Development Statistics:

- plays a pivotal role between Preclinical Research and Clinical Development

Predictive Analytics:

- responsible for bringing next generation 'big data' methods into the clinical development setting

East Asia:

- statisticians and statistical programmers who mainly work on late phase development including submission in East Asia

Late Development Statistics:

- strategic direction of statistical input for projects entering the late development phase, from after proof of concept until submission, launches and beyond

Statistical Programming:

- mainly focuses on the programming of the analyses supporting the clinical studies, regulatory submissions, regulatory inquiries and regulatory reporting

Standardization:

- ensures consistency of SSI deliverables by harmonizing the standards and best practices across early dev, late dev, and across all indications

SSI Roles Pertinent to Clinical Studies

Role	Responsibility	Role to role Interaction
Project Lead Statistician (PLS)	<ul style="list-style-type: none"><input type="checkbox"/> Responsible and accountable for statistical components of the program.<input type="checkbox"/> Leads the biometrics team and provides strategic direction to the project team.	<ul style="list-style-type: none"><input type="checkbox"/> Line manages CPStats and CTStats within the project team.<input type="checkbox"/> Works closely with PLP to ensure SSI meets agreed budget and timelines with quality.
Clinical Program Statistician (CPStat)	<ul style="list-style-type: none"><input type="checkbox"/> CPStat's lead statistical strategy for clinical studies and regulatory components related to submissions of indications.	<ul style="list-style-type: none"><input type="checkbox"/> Works closely with PLS to ensure alignment on submission strategy and statistical program conventions.<input type="checkbox"/> Frequent interaction with CTStats for review of SAPs, TFLs, and CSRs.
Clinical Trial Statistician (CTStat)	<ul style="list-style-type: none"><input type="checkbox"/> CTStat role encompasses all statistical related activities that are conducted/overseen by SSI.<input type="checkbox"/> Works with study project teams to ensure sound statistical principles are applied to clinical trials.<input type="checkbox"/> Ensures high quality of outputs and correct interpretation of study results.	<ul style="list-style-type: none"><input type="checkbox"/> CTStat reports directly to the PLS.<input type="checkbox"/> Consults often with CPStat and PLS to discuss adherence to program statistical conventions and to ensure statistical strategy is sound.<input type="checkbox"/> Liaises with STATP to assess quality of programming deliverables.
Project Lead Programmer (PLP)	<ul style="list-style-type: none"><input type="checkbox"/> Lead programmer on a compound.<input type="checkbox"/> Accountable for all programming aspects of the project.<input type="checkbox"/> Provides oversight and direction of programming activities within the project team.	<ul style="list-style-type: none"><input type="checkbox"/> Line Manages STATP's.<input type="checkbox"/> Works closely with PLS to ensure SSI meets agreed budget and timelines with quality
Statistical Programmer (STATP)	<ul style="list-style-type: none"><input type="checkbox"/> Responsible for programming activities of the trials, integrations, and safety reporting including programming of ADaM datasets and TFLs as well as PK and ADA data programming.<input type="checkbox"/> The STATP works with the joint UCB and CRO team to ensure standards are implemented on the study throughout ADaM and TFL programming and reviews for quality.	<ul style="list-style-type: none"><input type="checkbox"/> Reports Directly to PLP's.<input type="checkbox"/> Liaises with CTStats to assess quality of programming deliverables

Types of Studies

<u>Interventional Study</u>	<u>Non Interventional Study (NIS)</u>	<u>Post Authorization Safety Study (PASS)</u>	<u>Managed Access Program</u>	<u>Real world Evidence (RWE) Studies</u>	<u>Investigator initiated Studies (IIS)</u>
A study involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device).	A study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. Non-interventional studies are defined by the methodological approach used and not by the scientific objectives.	Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.	Provision of a medicinal product on a named patient basis or for a cohort of patients with chronic or serious debilitating disease, life threatening disease, or unmet medical need. The Unapproved Product is either undergoing clinical trials or subject of an application for a marketing authorization pricing negotiation, or experiencing temporary supply problems.	RWE Studies are studies conducted using data that are routinely generated or collected during health care delivery to understand the natural course of the disease, real-life treatment patterns and patient outcomes in the wider ecosystem of care.	A study initiated/proposed via an Unsolicited Request and sponsored and conducted by a party other than UCB, and for which the Sponsor and/or Investigator has specifically requested Support from UCB.

Internal Stakeholders



UCB Commitment

UCB is continuously working to advance science and embrace new knowledge, bringing passion and leadership to solving the challenges that matter to people living with severe diseases. We are leveraging scientific advances and new technologies in areas including genetics, biomarkers and human biology. Continually inspired by those we serve to bring differentiated solutions with unique outcomes that deliver tangible, positive impacts.

Our work is rooted in a culture of dialogue, collaboration and respect, allowing us to forge bonds with the people we serve and those who know their challenges best, ensuring that our work can have the greatest possible impact.



Inspired by patients.
Driven by science.

Thank you!

<https://www.ucb.com/>