



Curriculum Vitae

Personal information **Zhiyi You**

Work experience

Jan. 2025 – Chefkonsulent, Biostatistician, Danish Medicines Agency

- Evaluate statistical methodologies in MAA submissions and provide comments in the Assessment Report (AR), Overview, and List of Questions (LoQ)
- Attend pre-submission meetings with MAA applicant
- Participate in debates and discussions during CHMP meetings
- Share statistical expertise and insights with colleagues
- Participate in drafting, revising, and updating multiple ICH and EMA guidelines
- Supervise and mentor less experienced biostatisticians

Jan. 2024 – Dec. 2024 Specialkonsulent, Biostatistician, Danish Medicines Agency

- Provide scientific advice to pharmaceutical companies
- Assess MAA submissions, comment in AR and Overview & LoQ
- Attending submission meetings with MAA applicant
- Provide statistical consultancy to team members

Aug. 2019 – Dec. 2023 Biostatistician, Danish Medicines Agency

- Assess MAA submissions, comment in AR and Overview & LoQ
- Leading EMA CDISC data Pilot projects cooperating with Roche & Novo Nordisk using SAS
- Leading EMA GCP inspection Pilot projects using JMP Clinical and Pinnacle 21
- Conduct statistical analysis

Jan. 2018 – Jun. 2019 Scientific student assistant, Biostatistics, Novo Nordisk A/S

- Assisted protocol quality, and procedure improvements, provided statistical analysis, producing table, figures and listings, and reviewing for clinical outputs by using SAS Enterprise Guide, participated in preparation for result meeting presentations.

2012– 2017 Business analyst, Isken Aps & Ishus Aps, Denmark

- Budget control, providing business analysis and reports to senior management, supporting the development of business decisions

Education and training

2020 Copenhagen University, Survival analysis course for PhD

2016 – 2019 Lund University, Bachelor and Master degree in Statistics
Master's thesis: Analysis of Cryptocurrency volatility and statistical distributions

2008 – 2012 Lund University, Bachelor and Master of Science in Economics
Master's thesis: How Balanced Scorecard scale down into small organizations

Additional information

Publications

Use of CDISC data in the Danish Medicines Agency

February 2023

[Journal of the Society for Clinical Data Management 2\(3\)](#)

DOI:[10.47912/jscdm.163](https://doi.org/10.47912/jscdm.163)

Projects

- Leading EMA CDISC data Pilot projects cooperating with Roche & Novo Nordisk using SAS
- Leading EMA GCP inspection Pilot projects using JMP Clinical and Pinnacle 21

Memberships

Other Relevant Information