

The hardships of finding your way in biometrics

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ABSTRACT

The developing field of biometrics and the lack of long established positions in biometrics has led to a labyrinth of job titles and description. Recently the demand for biometric professionals with an interdisciplinary skill set in statistics, programming and clinical data management has increased. For professionals interested to enter the field of biometrics it is challenging to find a place in this complex system. The similar job titles with entirely different job descriptions and similar job descriptions corresponding to entirely different job titles lead to a great deal of unnecessary confusion. Therefore it is pertinent to have an overview of how the biometrics system in biotechnology and pharmaceuticals operates and has operated for the decades it exists. This paper identifies the changes and/or additions in desired skill sets for successful biometric professionals. With the increasing level of standardisation in biometric environments, standardising job titles is something worth considering.

INTRODUCTION

Imagine you have a background in a biological, medical, pharmaceutical or statistical field and you have a passion for computational science or maybe you have a background in computer science and a passion for life science related fields. You decide that you want to combine your expertise and your passion, which field you are going to explore is totally unclear to you at this point. The logical step is to investigate what the opportunities are which provide you the prospect of combining your professional qualities and your passion. Somehow you stumble upon biometrics, maybe from a friend. Either way, it sounds perfect! You have never heard of biometrics before, and the following question come to mind: What is biometrics exactly? Which positions can you apply for?

You start searching the internet for what opportunities are out there, requiring professionals with an interdisciplinary skill set in computational science and life science. You are enthusiastic and search for entry positions in biometrics. After a couple of minutes of searching you discover that there is another specialized field using the name biometrics, security based on biometric materials, and this is not exactly what you were aiming for. However additional hours of searching have resulted in numerous job titles – e.g. clinical programmer, statistical programmer, data scientist, (study) (clinical) data manager, (bio)statistician, database programmer, (clinical) data scientist – and corresponding job descriptions for biometrics in life science. Now the disarray is complete! The job descriptions of some of these job titles are almost identical. This might arise more questions than answers: Are these company job titles? Do these job titles encompass multiple specialties?

As a newcomer in biometrics these might be questions you have encountered and/or are still struggling with. The following sections will provide an overview and describe the hurdles you may encounter on your journey to your desired position and/or career. In the 'Tasks in Biometrics' section I will provide an overview of the different tasks captured by the biometric departments to provide a better perception of the possibilities.

BIOMETRICS

CLINICAL STUDIES

To get a better sense of the vital elements involved in a study and how biometrics fits in there. First you need to understand the basic elements of clinical research, Figure 1 presents an overview of a typical study team. As setting up and performing a study is a complex procedure, detailing the processes of clinical research is outside of the scope of this paper. Therefore data need to be processed, managed, analysed and reported/visualised, this is what biometrics specialises in. A study has three major components for biometrics: study set-up, study conduct and study closure. Throughout these three phases biometrics is responsible for the data related components of the study. As a newcomer it is pertinent you at least understand these aspects of biometrics involvement in a study.

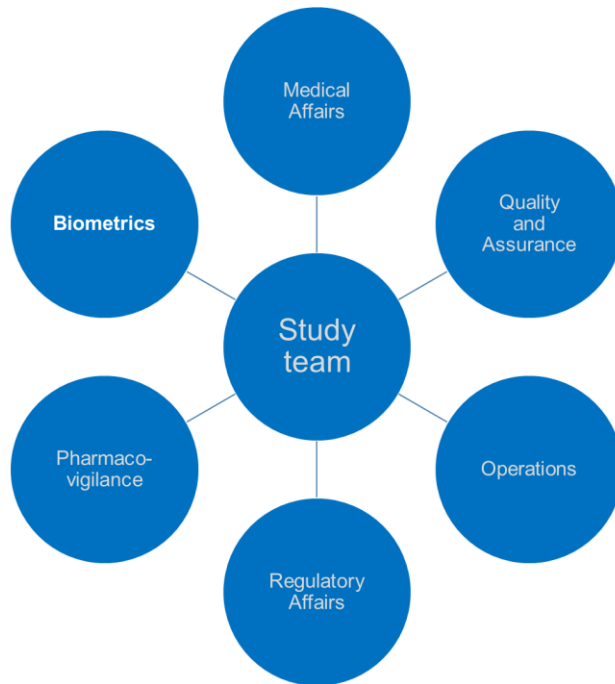


Figure 1. A general study team structure

STUDY DATA FLOW

At study start-up the department composes a plan (data management plan) on how, where and when to register as well as whom is authorized to handle these data and whom is responsible for the data. The data will be registered in an Electronic Data Capturing (EDC) system. Following the data entry in the EDC, the data are cleaned, this is a necessary step to assure the database(s) contain reliable data (information). When the data are sufficiently cleaned and validated the databases are ready to be locked (database lock). Locking the database means that there are no more alterations to the data, excluding extraordinary circumstances. The database is ready for analysis after database lock, these analysis might be any type of analysis relevant for the specific study. Subsequently the time has come for reporting and if satisfactory, the data are ready to be transferred to other department(s) e.g. medical writing and regulatory submission. All these data are managed and submitted according to the Clinical Data Interchange Standards Consortium (CDISC) standard. Figure 2 represents the data flow and which departments are involved.

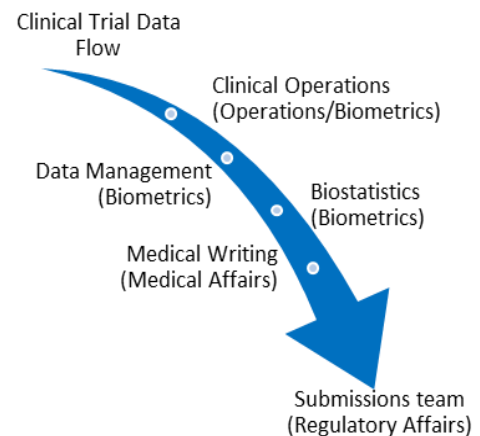


Figure 2. A rough overview of the data flow in clinical studies

TASKS IN BIOMETRICS

Now that we are clear on what biometrics is and its position in studies we will continue our journey: What do biometric professionals do exactly? Your job search has emanated various job titles and job descriptions, however it seems that the only available positions require a minimum of 3 years experience in biometrics. Thinking of how you are going to find an entry position and what the job tasks are in biometrics, you continue your search. In the following section we discuss the tasks allocated to the biometric departments' professionals.

(STUDY) DATA MANAGER

The (study) data manager is ultimately responsible for the data conduct and data storage, from the study start-up, statistical analysis to reporting. However the (study) data manager is intimately involved in the creation of the data management plan, data validation check and database lock. The data management plan contains protocols which are complementary to standard operating procedures (SOPs) and CDISC guidelines. The (study) data manager is an experienced biometrics professional with knowledge of regulatory requirements (CDISC, GCP, GLP), clinical data in general and statistical analysis. Furthermore, the (study) clinical data manager is an excellent communicator, good project manager and capable of working with timelines.

(CLINICAL) DATABASE PROGRAMMER

The database programmer is responsible for building the underlying structure of the database and creating the Case Report Form ((e)CRF) according to the standards provided in the data management plan. The database structure is

PhUSE 2016

closely related to the (e)CRF to ease data entry, data cleaning and data validation procedures. The database programmer has excellent programming skills (SAS®/ORACLE®/SQL® or other programming language), knowledge of clinical data and CDISC conventions (SDTM and ADaM models). Additionally, the database programmer is capable of following strict instructions, is capable of working with stringent timelines, possesses an analytical mind and has problem solving mentality.

DATA ENTRY/DATA MANAGER

Lately the data collection and entry tasks have provoked some confusion with regard to the vacancy job titles. The data entry specialist is mainly responsible for entering data from paper CRFs into the EDC system, however nowadays the data entry specialist position has become redundant by the introduction of the eCRF somewhere in the beginning of this decade. No more double data entry! The data manager checks if the data are complete, if the data are realistic (data cleaning and validation), the data manager is responsible for data collection where needed. The remaining tasks previously assigned to the data entry specialist might also be added to the data manager(s), depending on needs of the study and/or organisation. A data entry specialist possesses a keen eye for detail and good communication capabilities. A data manager possesses these qualities and has the knowledge of regulatory requirements (GCP, GLP & more), terminology. Moreover, the data manager has organisational competences, team working capabilities, and experience with clinical database systems.

(Bio)STATISTICIAN

Like the (study) data manager, is the (bio)statistician involved throughout the study. The (bio)statistician provides input on which analyses are going to be performed and which data need to be collected to be able to perform these analyses. Further is it the (bio)statistician's responsibility to write a SAP (Statistical Analysis Plan) and to provide overall advice on other aspects related to the study. The (bio)statistician is therefore a person with excellent knowledge of statistical methods, with some knowledge of statistical programs and CDISC models (in particular ADaM). Furthermore this professional possesses excellent communication capabilities.

STATISTICAL PROGRAMMERS

The statistical programmer is responsible for the execution of the SAP, the creation of the reports for submission or other purposes. The statistical programmer possesses good knowledge of statistics, excellent statistical programming capabilities (e.g. SAS, R, SPSS) and the ability to support study requirements. Just as important are the communication capabilities and the time management skills.

PROFESSIONALS IN THIS AGE AND TIME

As biometric departments rely heavily on regulations and computational science developments, any advancement in any of these two fields might tremendously affect operations of the biometric departments. Take the introduction of the eCRF, it has made a previously crucial position in the data flow redundant. However there have been other noticeable changes in relation to the capabilities of the biometric professionals. In all part of the medical/pharmaceutical community interdisciplinary fields have become more and more popular, consequently most members of these teams also have an interdisciplinary skill set.

DATA SCIENCE

The increasing computational capacity to collect, process and store data has resulted in a demand for professionals capable of managing, interpreting, analysing and visualising data also generally known as a data scientist. The increasing need to unravel new patterns and deriving meaningful contributions from existing data, is what a data scientist specialises in. This way of approaching data is very common in internet enterprises, financial markets and more industries. Just as in the other industries, biometrics might also benefit from deriving new insights from the already available data.

BIOMETRICS AND DATA SCIENCE

The amount of specific data collected in studies presents a world of information, perhaps alternative insights might present itself by employing this data science approach. But how does this fit in the biometrics approach? A (study) data manager, statistician or statistical programmer on their own, with their previously specified skill set in biometrics might not cut it as a data scientist. However when combining the skill set of the data manager, the statistician and the statistical programmer, this might result in a professional that would cater the managing, analytic and visualisation capabilities of e.g. a data scientist.

Carefully we are approaching the potential cause of the shift in competences and job descriptions. It seems biometrics has not yet found an efficient way to distinguish these interdisciplinary (data scientist) professionals from the established job titles. It might also be the case that the job titles will stay the same and the job descriptions will evolve overtime collectively. However for now the interwoven job titles where the (bio)statistician is a statistician and statistical programmer in one is becoming more and more popular, the same goes for the database programmer and the (study) (clinical) data manager.

CONCLUSION

We have gone through the data flow and job positions involved in studies and biometrics. If you were not familiar with biometrics or were not aware of the association of biometrics with clinical research, you should now have an indication of: how biometrics is positioned in a study team; how the biometrics team was/is structured: What the various tasks and job titles are. For newcomers, the change in the biometric team roles to a more multifaceted professional has caused confusion. This in regard to the relation of job titles and the responsibilities. Therefore it might be beneficial to unify and restructure the job titles just as most processes in biometrics.

ACKNOWLEDGEMENTS

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RECOMMENDED READING

Friedman, Lawrence M., et al. (2015), Fundamentals of Clinical Trials 5th ed., Switzerland, Springer International

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