



Biostatistician

Bio-economy Skills Profile



Building skills for Canada's bio-economy

About BioTalent Canada

Helping Canada's Bio-economy thrive globally

Canada is a world leader in biotechnology—the application of living organisms to industrial, agricultural, medical and other processes and products. To maintain and build on this leadership, the sector needs highly trained, job-ready people.

By acting as a national hub and central resource for employers, job-seekers, students, educators and government agencies, BioTalent Canada helps make this happen.

The opinions and interpretations expressed in this publication are those of the author and do not necessarily reflect those of the Government of Canada.



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About the BioTalent Canada bio-economy skills profiles

Biotechnology's fusion of science and business creates unique requirements for occupations in the sector. Executives and managers must have technical expertise; technical staff often need entrepreneurial skill sets. Occupational descriptions from other sources don't always fit the bio-economy context. That's why, in partnership with industry stakeholders, BioTalent Canada has developed skills profiles specific to the bio-economy including this description of the role biostatistician.

Occupational Definition

Biostatisticians design research studies and analyze data related to human health, animals or plants. They apply their knowledge of statistics, science and mathematics to gather and analyze data to help researchers answer questions. Biostatisticians collaborate and clearly communicate with staff, medical and scientific researchers in design, data collection, analysis and publication of study data, and provide overall statistical support, data processing, study design, and data analysis services. Their role is to compile an unbiased statistical analysis of data retrieved from clinical trials to assist investigators and researchers. They are responsible for overseeing the collection of data, applying statistical methodologies and communicating findings to facilitate decision-making. Once the raw data has been gathered, biostatisticians apply recognized standard statistical methodologies and use statistical software to turn the data into useful information.

Biostatisticians work as academics, for the government, in the biomedical field and other industries interested in analyzing the effects of treatments, environmental conditions and other factors on living things. They work for Canadian biotechnology companies of different sizes (i.e., small, medium, large) and in various biotechnology areas such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bioinformatics
- Bioproducts
- Biosciences
- Environment
- Food Processing
- Forestry
- Genomics
- Human and Animal health
- Industrial
- Life Sciences
- Medical Devices
- Natural Resources
- Nanotechnology
- Nutraceuticals
- Pharmaceuticals

Components of the skills profile

Every BioTalent Canada skills profile presents the areas of competence, tasks and sub-tasks associated with a specific occupation.

Area of competence (AC): This describes a major function or responsibility associated with the profession, trade or position.

Task: This is a specific, observable unit of work with definite start and end points. Tasks can be broken down into two or more steps and are generally performed in a limited period of time. Tasks and ACs are identified in behavioural terms, beginning with a verb that describes the applied behaviour.

Subtask: This is a distinct, observable activity that comprises the steps involved in a task.

Important Action/Performance Standard: This provides a criterion for assessing competence and may be used as a performance indicator.

Focus on competencies

The BioTalent Canada skills profiles are built around areas of competence because competencies are flexible, inclusive and linked directly to performance: they are the traits or qualities a professional must have to succeed in a given role within a given organization, and can be used for recruiting, professional development, curriculum planning and many other purposes.

How to use the profiles

The complete contents of this or any BioTalent Canada skills profile are unlikely to be used for any one position. Because they are comprehensive, they include every area of competence, task and subtask that could be required for a specific occupation. In reality, the definition of a given job will encompass a narrower subset of the profile. Hiring organizations must choose the elements of the profiles that are relevant to their businesses—and tailor those elements as necessary to more precisely describe their particular job requirements.

The profiles can be put to many uses:

- **Employers** can use them to develop job descriptions, performance evaluations, professional development, succession planning, team building, target skills needed, and recruitment plans.
- **Job seekers** can use them to tailor their resumes, prepare for interviews, see job descriptions and identify additional professional development needs.
- **Educators** can build industry-oriented curricula from the profiles to produce job-ready graduates.
- **Students** can enhance their understanding of employers' expectations and choose the right educational programs to equip themselves with the skills for success.

Scenario

The following illustrates how an employer might use the BioTalent Canada skills profiles to identify professional development priorities for his or her team.

Step 1

The employer would review the ACs for each occupation and identify which apply to the related positions within his or her company, omitting those that are not relevant.

Step 2

Under the selected ACs, the employer then notes which of the associated tasks, subtasks and important actions are relevant to that specific position within his or her business.

Step 3

Now with a complete, tailored profile, the employer can assess employee performance. Needs areas are easily identified and defined—to a significant depth of detail.

Step 4

Based on the needs analysis, the employer can either develop or seek out professional development programs that address employee needs areas.

Situational Analysis

A biostatistician is a statistician with additional education in the biological sciences who applies statistical methodologies and knowledge of statistics, science and mathematics to scientific research in areas related to human health, animals, plants and microorganisms. They play key roles in designing research studies – from helping to formulate the questions that can be answered by data collection to the decisions on how best to collect the data – and in analyzing/interpreting the resulting data. Biostatisticians work with colleagues to share their findings by writing and publishing papers on the work, and presenting findings and results at conferences.

Biostatisticians need to be able to approach project analysis in a creative, but logical and analytical, manner, formulating scientific questions or problems into mathematical terms. They usually have several projects underway simultaneously, so planning, setting priorities, being organized and multi-tasking are all attributes of an accomplished biostatistician. They will also have well developed understanding of how computers can be used to handle and analyze data, and be comfortable working with computers.

Biostatisticians typically have extensive backgrounds in mathematics and science as well as statistics. Most positions require either a master's or a doctorate degree in statistics, biostatistics or mathematics supplemented with several years of relevant experience. A successful biostatistician will be inquisitive, intuitive, analytical, intellectually rigorous, self-disciplined and perseverant with the ability to work independently or as part of a team. They enjoy working with others and are flexible team players. They frequently work with a wide variety of professionals in technical, clinical, marketing, developmental design, and executive departments. Well developed interpersonal and communication skills (both written and verbal) enable biostatisticians to interact and collaborate with clinicians, scientists, and other study stakeholders. They must be able to explain complex information in a clear and concise way that non-statisticians can understand, using both technical and business terminology.

Job advertisements and other data suggest that employers look for some level of relevant experience working as a statistician/biostatistician when staffing biostatistician positions. The level of experience required is typically linked to the level of the position and the educational qualifications of the candidate. For example, an entry level position may require 2 – 5 years experience dependent on educational qualifications while a more senior level position may require 5 - 8 yrs experience dependent on educational qualifications.

Essential Skills

The most important Essential Skill(s) for this Profile: ✓					
	Reading Text		Thinking Skills – Problem Solving		Working With Others
	Document Use		Thinking Skills – Decision Making	✓	Computer Use
	Writing		Thinking Skills – Critical Thinking		Continuous Learning
✓	Numeracy		Thinking Skills – Job Task Planning & Organizing		
✓	Oral Communication		Thinking Skills – Significant Use of Memory		
			Thinking Skills – Finding Information		

Biostatisticians apply their numeracy skills (knowledge of statistics, science and mathematics) to gather and analyze data to help researchers answer questions. They need strong oral communication skills to collaborate with staff, medical and scientific researchers in design, data collection, analysis and publication of study data. They also need well developed computer skills to provide overall statistical support, data processing, study design, and data analysis services.

Language Benchmarks

The majority of communications tasks associated with the required competencies and activities of a competent Biostatistician were found to be between Canadian Language Benchmark levels 9 – 12. This finding is based on a limited sampling of representatives in industry. The actual language benchmark requirements for this occupation within an organization will be subject to the organization’s requirements, and the definition of the occupational role within the organization.

Competency Profile

A Biostatistician must be able to:

A. Provide support to a research study

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Contribute to study design	1.1. Actively participate in the study concept design and development of objectives.	Appropriate regulatory guidelines (e.g. International Conference of Harmonization [ICH] (chapter E9))
	1.2. Provide statistical and data management input into protocol development.	
	1.3. Co-author with research colleagues to design and develop protocols.	
	1.4. Oversee the development of Data Management Plans (DMPs).	
	1.5. Provide statistical input into the design of forms and templates to be used in the study, e.g. Case Report Forms (CRFs).	
	1.6. Oversee development, review and testing of study forms and templates.	
	1.7. Review clinical study and statistical/data management documents generated by others.	
	1.8. Provide statistical/mathematical input to the development and maintenance of study standards, standard operating procedures (SOPs) and guidelines.	
	1.9. Assist in defining the objectives for the study.	
	1.10. Collaborate with researchers to determine sample size calculation.	
2. Participate in study execution	2.1. Participate in study meetings, e.g. clinical trials, investigator meetings, site monitor/coordinator training sessions.	International Conference on Harmonization (ICH) (Chapter E9)

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.2. Write statistical and data management sections of the joint medical and statistical study reports.	
	2.3. Ensure investigators and site personnel are trained on data management requirements and procedures.	
	2.4. Act as the primary knowledge holder of sponsor specific requirements.	
	2.5. Oversee projects for a sponsor company and/or for given therapeutic/research areas.	
	2.6. Address statistical and data management questions and/or concerns raised at study meetings.	
	2.7. Monitor statistical programming/data management to ensure that the statistical analysis plan (SAP) is followed as the study progresses.	
	2.8. Adhere to study standards, standard operating procedures (SOPs) and guidelines.	
3. Support study completion	3.1. Provide data/analyses for inclusion in the registration documents.	Appropriate regulatory guidelines
	3.2. Share results and findings with colleagues and team members in group meetings.	
	3.3. Produce written reports for internal stakeholders.	
	3.4. Share lessons learned with management and team members.	
	3.5. Ensure compliance with standard operating procedures (SOPs) for the handling and archiving of data stores.	
	3.6. Co-author and/or contribute to publications	

A Biostatistician must be able to:

B. Develop the statistical analysis components of a protocol

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Conduct background research	1.1. Develop an understanding of registration requirements (both local and international requirements).	
	1.2. Identify potential research areas appropriate to the study goals and objectives.	
	1.3. Analyze statistical/mathematical research trends and directions.	
	1.4. Determine appropriate statistical approach/methodology for the study.	
	1.5. Select the appropriate approach/methodology for the study.	
2. Address the requirement for a separate Statistical Analysis Plan (SAP)	2.1. Review and apply standard operating procedures (SOPs)/guidelines/best practice on statistical analysis plan (SAP) development if necessary.	
	2.2. Develop an overview of the study.	
	2.3. Document the objective and goals of the study based on the protocol.	
	2.4. Develop the table of contents	
	2.5. Determine the expected content and format of tables to be included in the statistical analysis plan (SAP).	
	2.6. Define roles and responsibilities	
	2.7. Identify relevant regulations, legislation and guidelines that impact the development of the statistical analysis plan (SAP).	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.8. Address the detailed technical analysis steps (e.g. programming code, formulae) required to achieve the analysis that is outlined in the protocol.	
3. Document design considerations	3.1. Outline the scope of the study.	
	3.2. Define the scope of the statistical analysis.	
	3.3. Calculate the sample size as per the previously agreed upon methodology.	
	3.4. Document inclusion/exclusion criteria.	
	3.5. Identify test devices.	
	3.6. Develop reporting requirements (e.g. clintrials.gov).	
4. Outline the study schema	4.1. Identify study procedures.	
	4.2. Document study timelines and milestones.	
	4.3. Identify data requirements at each milestone.	
	4.4. Define study procedures to be completed at each milestone.	
	4.5. Document assumptions used in developing the study schema.	
5. Define study endpoints	5.1. Confirm study objectives with study team.	
	5.2. Define each endpoint to measure objectives adequately.	
	5.3. Determine the endpoints to be measured at each milestone in the study.	
	5.4. Identify transformations that may need to be applied to the data gathered for each endpoint.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.5. Indicate how missing data/information will be handled at each endpoint.	
6. Identify statistical tests to be used	6.1. Discuss how data from different populations will be handled (i.e. data pooling).	
	6.2. Define the various analysis populations.	
	6.3. Document the statistical methods to be used in the study.	
	6.4. Identify the appropriate statistical test(s) and analyses to be completed for each objective.	
	6.5. Determine how changes to the planned analyses will be handled.	
7. Document study definitions	7.1. Select the definitions and the terms to be used in the study.	
	7.2. Define the parameters for the endpoints to identify alternate courses of action around the data gathering and the analysis.	
8. Undertake steps for review and approval of a statistical analysis plan (SAP)	8.1. Circulate the draft statistical analysis plan (SAP) to research and statistical colleagues for review and feedback.	
	8.2. Update and adjust based on feedback received.	
	8.3. Submit draft statistical analysis plan (SAP) to the Study Executive for approval.	
	8.4. Address concerns and issues raised during the approval process.	
	8.5. Communicate and circulate the approved draft statistical analysis plan (SAP) to the study team.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	8.6. Submit the approved statistical analysis plan (SAP) for inclusion in the registration dossier, if applicable.	

A Biostatistician must be able to:

C. Analyze and interpret study data

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Support collection of the study data	1.1. Define and document data collection protocols/standard operating procedures (SOPs).	
	1.2. Ensure study personnel understand data collection protocols/standard operating procedures (SOPs).	
	1.3. Oversee use of computer/specialist computer software applications to gather data wherever practical.	
	1.4. Monitor incoming data as the study progresses regarding frequency, timeliness and completeness.	
	1.5. Identify gaps.	
	1.6. Advise study personnel of findings/concerns regarding data collection.	
	1.7. Work with study personnel to address gaps.	
	1.8. Ensure the study data is stored in accordance with company guidelines and policies regarding sensitive/confidential information.	
2. Apply statistical methods and tests	2.1. Verify integrity of the collected study data/information.	
	2.2. Identify and resolve identified inaccuracies/anomalies.	
	2.3. Use specialist computer software to analyze data and to produce analysis results.	
	2.4. Apply the statistical tests and methods outlined in the approved statistical analysis plan (SAP).	
	2.5. Generate information/charts/graphics/tables summarizing analysis findings.	
3. Assess analysis findings	3.1. Review analysis findings.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.2. Assess implications of analysis findings in terms of study objectives, hypotheses and design	
	3.3. Evaluate need for further study or adjustments based on analysis results	
	3.4. Advise study management of all results/findings, expected and unexpected	
	3.5. Share analysis findings with study personnel, Executive management and stakeholders	
4. Report findings to the internal organization	4.1. Develop charts/tables/content as described in the approved statistical analysis plan (SAP)	
	4.2. Co-author report with the research team members summarizing study findings and recommendations	
	4.3. Circulate draft report to study personnel for review and comment	
	4.4. Update draft report based on feedback	
	4.5. Submit study report to Study Executive for approval	
	4.6. Address concerns and issues raised during the approval process	
	4.7. Communicate approval of the study report	
	4.8. Submit the approved study report for inclusion in the registration dossier	

A Biostatistician must be able to:

D. Advance the research agenda

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Assess statistical outputs	1.1. Evaluate data/information objectively.	
	1.2. Apply due diligence.	
	1.3. Evaluate potential for continued development/commercialization.	
	1.4. Seek internal and external input.	
	1.5. Prepare recommendations and report on moving research outcomes forward in the development process.	
2. Contribute to the registration dossier	2.1. Understand registration requirements (both local and international requirements as needed).	
	2.2. Prepare documents required for registration.	
	2.3. Complete administrative documents.	
	2.4. Submit dossier documents for approval.	
	2.5. Provide support to the internal team for statistical components of the dossier.	
3. Present results to the scientific community	3.1. Respect corporate guidelines re: intellectual property and sensitive business information.	
	3.2. Share results and findings with colleagues and key opinion leaders (KOLs) in group meetings.	
	3.3. Write original papers outlining research.	
	3.4. Co-author papers describing the results in reputable scientific journals.	
	3.5. Provide support for the presentation of findings at scientific/medical conferences.	

A Biostatistician must be able to:

E. Provide expert/advisory services

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Serve as an in-house consultant	1.1. Maintain networks with other experts in the appropriate field.	
	1.2. Stay current with pertinent legislation and regulations.	
	1.3. Stay current with the business strategy.	
	1.4. Share 'lessons learned' (both positive and negative) from past pre-clinical studies and clinical/field trials.	
	1.5. Communicate leading practices with respect to trial design, data collection and analysis.	
	1.6. Update knowledge and understanding by reading scientific/medical/statistical journals and attending professional conferences.	
	1.7. Collaborate with academia to apply the results of research and develop new statistical techniques.	
2. Act as a peer reviewer	2.1. Evaluate content of a proposed publication.	
	2.2. Provide a critique of a proposed publication.	
	2.3. Make suggestions to improve quality/scientific basis of a proposed publication.	
	2.4. Identify overlooked ideas, theories or bodies of knowledge pertinent to the content of a proposed publication.	
	2.5. Highlight shortcomings of an proposed publication e.g. incomplete conclusions, faulty logic.	
3. Maintain status as a 'recognized	3.1. Publish in peer reviewed journals.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
authority'	3.2. Act as presenter at national conferences.	
	3.3. Maintain a strong publication record.	
	3.4. Pursue recognition among colleagues as a subject matter expert.	
4. Mentor and coach peers and the management team	4.1. Share expert knowledge and experience.	
	4.2. Provide guidance and support.	
	4.3. Provide contacts and open networks.	
	4.4. Offer positive reinforcement and recognition.	
	4.5. Provide specialized training in an area of applied statistics and mathematics.	

A Biostatistician must be able to:

F. Demonstrate generally accepted management capabilities

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply generally accepted management principles and techniques	1.1. Align management and leadership style with the corporate culture and objectives.	
	1.2. Promote the use of generally accepted management principles and techniques.	
	1.3. Create opportunities for information sharing across the study team - e.g., regular meetings, governance structure.	
	1.4. Comply with corporate policies and guidelines.	
	1.5. Ensure the procedures and structures are in place to achieve goals.	
	1.6. Establish the appropriate framework for evaluating performance and progress to plan.	
	1.7. Monitor and measure progress and performance.	
	1.8. Establish reporting schedule and distribution listing for regular reporting.	
	1.9. Keep team informed of progress and performance.	
	1.10. Provide coaching, mentoring and training to staff as required.	
2. Apply project management leading practices	2.1. Develop and work to a documented project plan (individual projects and collaboratively on larger initiatives).	
	2.2. Understand management expectations and set milestones accordingly.	
	2.3. Determine the level and nature of resources needed to support the project plan.	
	2.4. Administer project budget.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.5. Monitor progress to plan and achievement of project milestones.	
	2.6. Revisit and revise timelines, as required.	
	2.7. Identify emerging risks, issues and concerns.	
	2.8. Mitigate identified risks, issues and concerns and monitor to ensure the resolution of issues.	
	2.9. Report on performance to the project plan and recommended actions to address variances to plan.	
3. Identify and protect intellectual property	3.1. Understand corporate policies, guidelines and procedures pertaining to intellectual property.	
	3.2. Identify work considered to be intellectual property.	
	3.3. Take the necessary actions to protect intellectual property.	
4. Protect sensitive/confidential information	4.1. Identify those records which meet the definition of sensitive information under <i>Personal Information Protection and Electronic Documents Act (PIPEDA)</i> .	
	4.2. Assure maintenance of confidentiality of the information.	
	4.3. Identify personnel with access to sensitive information.	
	4.4. Communicate confidential information appropriately to those who have a functional 'need to know'.	
	4.5. Store and secure confidential information in observance of applicable laws and company policies/procedures.	
5. Use computers to analyze/manage data and information	5.1. Establish and/or use a formal system for computerized data/information collection, storage, access, retrieval, archiving and disposition.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.2. Ensure programs for data cleaning and data management are developed and implemented.	
	5.3. Demonstrate proficient computer capabilities and abilities with standard business suite products e.g. Microsoft Office, and statistical programs such as SAS, Splus, SPSS.	
	5.4. Apply statistical programming skills to analyze study datasets.	
	5.5. Use SAS data files and Excel databases to organize data/information.	
	5.6. Use statistical sample size calculation software to develop sample size recommendations.	
	5.7. Generate reports, presentations and manuscripts using computer-based processing, analysis and presentation of research and study data and information.	
	5.8. Incorporate understanding of standards for analyzing data and management of data, if applicable (e.g., Medical Dictionary for Regulatory Activities (MedDRA), World Health Organization (WHO)).	Medical dictionary for regulatory affairs (MedDRA), World Health Organization (WHO)
6. Manage work activities	6.1. Use materials and resources in a cost effective manner.	
	6.2. Administer budgets.	
	6.3. Oversee temporary personnel.	
	6.4. Apply continuous quality improvement techniques and risk management processes to ensure quality of statistical services.	
	6.5. Follow established policies and procedures.	
7. Establish effective working relationships	7.1. Work collaboratively with team members and others.	
	7.2. Share current knowledge with new colleagues.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.3. Recognize the skills and abilities of others	
	7.4. Show respect.	
	7.5. Accept and appreciate different ways of doing things.	
	7.6. Engage colleagues through proactively soliciting and sharing information.	
8. Encourage team-building	8.1. Facilitate team planning efforts.	
	8.2. Work towards measurable objectives.	
	8.3. Implement changes, as required.	
	8.4. Assign responsibilities appropriately (level, background/experience, expertise).	
	8.5. Empower people.	
	8.6. Promote accountability.	
	8.7. Participate in team building exercises.	

A Biostatistician must be able to:

G. Apply professional practices

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Comply with established policies, procedures and protocols	1.1. Maintain confidentiality (e.g., data, records, intellectual property, client information).	
	1.2. Practice and adhere to generally accepted statistical/mathematical practices.	
	1.3. Follow established corporate protocols and procedural documentation (e.g., policies, procedures, standard operating procedures (SOPs), test procedures).	
2. Comply with all applicable regulations and legislation	2.1. Know, understand and adhere to applicable rules, regulations and legislation e.g. International Conference on Harmonization (ICH), <i>Food and Drug Act</i> (FDA, European Medicines Agency (EMA)).	
	2.2. Review relevant literature.	
	2.3. Analyze prevailing legislation/regulations and capture parameters/controls relevant and/or applicable to studies.	
	2.4. Work within regulatory framework.	
	2.5. Reach agreement with external statistical stakeholders on statistical analysis procedures.	
3. Demonstrate statistical analysis skills	3.1. Employ various statistical procedures and advanced analytical techniques such as categorical data analysis, exploratory and graphical methods, analysis of variance, correlation analysis, multiple linear regression, time series analysis, logistic regression, survival analysis, spatial analysis, or non-parametric methods.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.2. Recommend appropriate statistical procedures or techniques for analyzing data.	
	3.3. Leverage knowledge of commonly used coding systems to develop statistical analysis plans and create statistical and clinical study reports (e.g., Medical Dictionary for Regulatory Activities (MedDRA)).	
	3.4. Develop sampling methods, determine sample sizes and define sub-groups of populations to be studied.	
	3.5. Work with a wide variety of data structures, coding schemes and data sources.	
	3.6. Manage and link datasets including large complex datasets.	
	3.7. Analyze datasets using statistical programs	
4. Demonstrate medical/scientific/regulatory knowledge and understanding	4.1. Apply knowledge of the research settings and trial monitoring, as required.	
	4.2. Apply knowledge of global pharmaceutical regulatory requirements where appropriate (<i>Food and Drug Act</i> (FDA), International Conference on Harmonization (ICH) etc.).	
	4.3. Leverage knowledge of the specific medical/scientific field of study.	
	4.4. Apply experience working with medical or scientific data to define a meaningful objective in the protocol and aid in interpretation of study reports and other contributions to regulatory documents.	
	4.5. Apply knowledge of ethics to study design	
5. Demonstrate professional integrity	5.1. Report findings and results accurately and honestly.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.2. Respect confidentiality (e.g., data, records, intellectual property, client information).	
	5.3. Take responsibility for actions and decisions.	
	5.4. Accept accountability for outcomes of actions and decisions.	
	5.5. Maintain high standards in practice.	

A Biostatistician must be able to:

H. Communicate

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Communicate with diverse audiences	1.1. Articulate clearly in written and oral communication	
	1.2. Use different styles of communication appropriate to the audience	
	1.3. Listen actively	
	1.4. Make presentations	
	1.5. Apply terminology	
	1.6. Negotiate	

A Biostatistician must be able to:

I. Demonstrate personal competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Demonstrate leadership	1.1. Focus on goals and objectives.	
	1.2. Demonstrate commitment.	
	1.3. Promote ethical behaviour and integrity.	
	1.4. Demonstrate balanced judgment.	
	1.5. Show and promote mutual respect.	
	1.6. Promote trust and honesty.	
	1.7. Accept accountability.	
	1.8. Contribute proactively.	
2. Demonstrate critical thinking/problem solving	2.1. Identify the problem.	
	2.2. Apply logical and methodical approach to identify and assess the cause(s) of the problem.	
	2.3. Develop and assess options to address the problem.	
	2.4. Apply knowledge, training and creativity to determine the appropriate course of action.	
	2.5. Oversee implementation of the selected course of action.	
	2.6. Evaluate the effectiveness of the selected course of action.	
	2.7. Solicit input from professional colleagues.	
3. Set priorities	3.1. Reference critical information when setting priorities (e.g. business strategy).	
	3.2. Establish criteria to facilitate priority setting, such as risk, time-sensitivity, investment required, etc.	
	3.3. Assess and defend available resources and redistribute work/assignments, as appropriate.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.4. Maintain awareness of time-sensitive issues and critical deadlines.	
	3.5. Keep goals and objectives in mind.	
	3.6. Multi-task where possible and practical.	
	3.7. Communicate priorities to team members/relevant personnel.	
	3.8. Review and adjust established priorities as appropriate.	
4. Organize work	4.1. Think ahead and anticipate.	
	4.2. Plan work schedule according to tasks and availability of tools.	
	4.3. Demonstrate effective time management.	
	4.4. Set priorities and objectives.	
	4.5. Identify and manage resources needed to complete work.	
	4.6. Establish processes/systems/methodologies to enhance effectiveness.	
	4.7. Recognize, develop, and use hard copy and electronic templates and forms	
	4.8. Update templates/forms as required.	
	4.9. Support use of the templates/forms with standard operating procedures (SOPs), help aids, education and examples.	
5. Manage multiple tasks	5.1. Recognize competing priorities.	
	5.2. Divide time appropriately.	
	5.3. Determine the appropriate level of effort for a task.	
	5.4. Identify and manage resources to assist in completing tasks.	
	5.6. Monitor progress.	
	5.7. Reset priorities in accordance with changing timelines and requirements.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
6. Maintain adaptability	5.8. Delegate, when possible	
	6.1. Show flexibility in resolving workplace and career challenges.	
	6.2. Adapt to rapidly changing situations.	
	6.3. Apply existing skills to new situations.	
	6.4. Retain composure in stressful situations.	
	6.5. Recognize that change initiated in one area will impact on other areas.	
	6.6. Contribute to and work effectively in a changing environment.	
7. Embrace continuous learning and development	6.7. Consistently search for improvements.	
	7.1. Allocate time for continuous learning.	
	7.2. Identify opportunities for continuous learning.	
	7.3. Build on and share 'lessons learned' from past research efforts with statistical colleagues.	
	7.4. Keep abreast of relevant statistical techniques, science and technology.	
7.5. Nurture the ability and enthusiasm to learn new skills and techniques.		

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The Board of Directors is composed of experts in the field of HR, CEOs, CFOs and CSOs from across Canada with extensive financial and industry experience representing companies and organizations in Canada's bio-economy. BioTalent Canada is not a membership organization and therefore relies on the guidance provided by its dedicated volunteer Board of Directors.

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