**Below, you'll find a "justification letter" template — a letter to your supervisor explaining all the benefits you'll get from attending the Virtual *DIA/FDA Biostatistics Industry and Regulator Forum,* how they will make you a better employee and help advance your organization.**

**This general template will get you started while allowing you to customize it to you and your organization's particular needs.**

**<Date>**

Dear <**Supervisor’s name>,**

This forum brings together a global community of professionals at all levels, all with a common goal of statistical thinking to inform policy, regulation, development, and review of medical products in the context of the current scientific and regulatory environments including pharmaceuticals, biologics and biosimilars, combination products and devices, and generics. The *DIA/FDA Biostatistics Industry and Regulator Forum* provides the greatest opportunity to meet with people from around the world, share views and knowledge, network, and build new relationships.

Numerous attendees, including industry professionals, clinicians, patient representatives, and regulatory agency representatives from around the globe, will attend and present at this event. In addition, I will have access to the FDA/Industry team working side-by-side with today’s experts in each session to present a 360-degree perspective of statistical design, analysis, and methodological approaches.

While attending this forum, I will be able to join leading edge discussions: statistical analyses in COVID-19 interrupted trials and therapeutic/vaccine trials, supplementation of RCT with RWD data, the FDA RCT DUPLICATE Project, PDUFA 7 and GDUFA 3, Complex Innovative Designs (CID) and FDA CID Pilot updates, Model Informed Drug Development (MIDD), and ICH E20 (Adaptive Clinical Trials) will be among the topics explored.

**<select interest areas applicable to you>**

* Biotechnology
* Clinical Data Management/eClinical
* Comparative Effectiveness/Health Technology Assessment
* Clinical Safety/Pharmacovigilance
* Clinical Research
* eClinical
* Pharmacology
* Quality Assurance, Control
* Regulatory Affairs
* Research and Development
* Study Endpoints/Clinical Outcomes Assessments
* Statistics

I am seeking your support in attending this forum. The registration fees, travel expenses, and per diem are estimated below.

Registration Fee: **<$XXX> see below**

**Registration Fees**

|  |  |
| --- | --- |
| **Early Bird Rates Through February 18** | **Member** |
| Academic/Charitable/Non-Profit (Full Time) | $575 |
| Government (Full Time) | $350 |
| Industry | $1,149 |
| **Standard Rates After February 18** | **Member** |
| Academic/Charitable/Non-Profit (Full Time) | $700 |
| Government (Full Time) | $475 |
| Industry | $1,275 |

Student Rate: $400
Patient/Patient Advocate Rate: $400

Thank you for taking the time to review this proposal. By attending the Virtual *DIA/FDA Biostatistics Industry and Regulator Forum*, having the opportunity to develop my skills, gain knowledge, and establish key contacts will be a valuable investment for my profession, colleagues, and **<insert name of your organization here>.**

Sincerely,