



November 1, 2022

Launchit Ventures Inc. a HealthTech venture studio, is announcing the launch of its latest venture, Otium Regulatory Inc., and its flagship product Regulatory DocWriter<sup>TM</sup>!

Regulatory DocWriter<sup>TM</sup> is the first online document writer built specifically for regulatory documents. It streamlines the most time-consuming stages of setting up Investigator Brochures (IBs), Clinical Study Reports (CSRs), Clinical Study Protocols (CSPs), Informed Consent, Trial Disclosure Forms, and similar documents.

Medical writing software is a must-have; however, until now medical writers had few good options. There has not been any software designed to efficiently reduce the time required to produce regulatory documents. Regulatory DocWriter™ provides considerable time savings for documentation of Phase 1-4 Clinical Studies, Bioequivalence Studies, and Medical Device Documents.

Investigational new drugs require a significant number of regulatory documents written for the submission package, and the process often takes multiple years. This process is not only slow, but hampered by inconsistencies between the writers and reviewers that all must contribute to the final package. A recent analysis found that 69% of Phase 3 protocols required one or more substantial amendments, with each amendment averaging a delay of 3 months and increasing costs by \$535,000¹. These delays are expensive, time consuming, and often avoidable.

Otium's Regulatory DocWriter™ is medical writing software targeted to both reduce the time required to create regulatory documents, and to reduce errors and inconsistencies.

This venture is a partnership between Launchit Ventures Inc. and Laconic Medical Writing Inc., a Canadian medical communications company.

**Laconic Medical Writing Inc.** provides medical communication services for the preparation of regulatory documents, scientific, and medical publications, patient education material, and much more. They strive to communicate medical and scientific

<sup>&</sup>lt;sup>1</sup> No End in Sight for Trial Complexity, CSDD Report Reveals (<a href="https://www.centerwatch.com/articles/25921-no-end-in-sight-for-trial-complexity-csdd-report-reveals">https://www.centerwatch.com/articles/25921-no-end-in-sight-for-trial-complexity-csdd-report-reveals</a>)





information concisely and effectively. To offer clients a full range of services, with the best expertise possible, they have a roster of biostatisticians, regulatory associates, study start-up specialists, and data management specialists that assist with document development.

Launchit Ventures Inc. is a HealthTech venture studio that offers a new model for entrepreneurship, combining company building with venture funding, to develop new businesses faster and with less risk. We partner with researchers, entrepreneurs, industry veterans, and others who have great ideas but need support and expertise to commercialize them. The Launchit Ventures team and its partners bridge the gap between a founder with an idea and the actual reality of getting a HealthTech start-up product or service into the market.

More information on the Otium Regulatory DocWriter™ can be found at <a href="https://www.otium.digital/">https://www.otium.digital/</a>.

More information on the partners behind the venture can be found at <a href="https://launchitventures.com">https://launchitventures.com</a> and <a

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