Wemedoo
Clinical Information Specialists

WT02 Study Proposal

LMN-0801 Obesity Study

Lumen Bioscience

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1. Reference

This offer is based on a bid solicitation by Lumen Bioscience for Oomnia software study-by-study (SBS) licensing and hosting and Wemedoo services related to the following clinical trial protocol:

Sponsor:	Lumen Biosciences
Study Title:	A Dose-Ranging Study Evaluating the Safety and Efficacy of LMN-0801 for Weight Loss (working title)
Short Title:	WT02
Protocol Version and Date:	Version 1.0 (21 Oct 2024)
Registration No.:	TBD

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2. Introduction

2.1. Executive Summary

Lumen Biosciences is an innovator in the development of innovative biologics, addressing critical unmet medical needs in areas such as C. difficile infections, inflammatory bowel disease (IBD), obesity, and cardiometabolic diseases. Backed by strategic partnerships with the Bill & Melinda Gates Foundation, BARDA, DARPA, the U.S. Department of Defense, and the National Institutes of Health (NIH), Lumen is poised to revolutionize healthcare through innovative science and robust funding.

Clinical trials are the backbone of drug development, yet they are often plagued by inefficiencies, rising costs, and fragmented systems. For Lumen Biosciences, managing a diverse pipeline—from Phase I exploratory studies to large-scale Phase III trials—requires a solution that is both flexible and scalable.

To support Lumen's ambitious growth and pipeline expansion, the Wemedoo oomnia platform offers a unified, scalable solution designed to streamline clinical trial operations, reduce costs, and accelerate timelines.

This proposal introduces a tailored flexible study-by-study pricing model to meet Lumen's diverse needs. This model is idea for Lumen Biosciences, it offers modular access while meeting expectations and reducing commitment at the initial stage of the relationship between Lumen and Wemedoo.

2.2. Benefits of Oomnia

The oomnia platform, developed by Wemedoo, is a comprehensive clinical trial ecosystem that integrates advanced tools to streamline every phase of Protocol WT02. Unlike fragmented solutions from competitors, oomnia delivers end-to-end unification—from trial design to data submission—with a single sign-on, and a simple intuitive interface. Here is how it meets and exceeds the requirements of Lumen Biosciences and the WT02 study:

- **Intuitive EDC:** oomnia supports multiple EDC document types including eCRF with built-in randomization and allocation to treatment, autogenerating electronic SAE Report forms with streamlined embedded regulatory workflows, as well as advanced features like custom electronic Protocol Deviation Logs. Once created, EDC documents such as the eSAE Report form and ePDL can be reused for future studies.
- **Randomization and Trial Supply Management (RTSM)**: The RTSM module supports automatic stratified randomization by BMI (<35 vs ≥35) and gender directly within the eCRF while automatically tracking IMP and notifying stakeholders of critical activities. As part of the unified system, it requires no additional time to integrate the eCRF and RTSM.
- **Seamless Device Integration**: oomnia connects directly to the Hologic Horizon DXA via HL7/FHIR and the Withings scale via RESTful APIs, ensuring real-time capture of fat/lean mass and at-home weight data with automated validation. The data can automatically be transferred to and integrated with participant eCRFs or other EDC documents, allowing for immediate access and review by the study team. As the Withings scale has bi-directional data transfer capabilities, notification can be directly sent to participant via the scale.
- **Patient-Centric Assessments**: Electronic Clinical Outcome Assessments (eCOA) and Patient-Reported Outcomes (ePRO) tools enable precise tracking of clinical endpoints and patient experiences, optimized for obesity research.
- **eTMF**: The built-in eTMF ensures that all stakeholders have access to essential documents and can track their filing without ever leaving the system. The structure of the oomnia eTMF has been fundamentally created on the CDISC-TMF Reference model, however it can be adapted to any model necessary, and there after reused for subsequent studies.

- **Real-Time Insights**: The oomnia unified system records all data and metadata, unparalleled advanced analytics using our integrated BI tools with statistical capabilities. The dashboards provide Lumen with immediate access to trial progress, data trends, and compliance metrics, enhancing decision-making across and between all system modules.
- **CTMS**: With unparalleled EDC capabilities and real-time insights, the oomnia CTMS can be custom configured to the needs of Lumen Biosciences. Once configured, it can be reused for subsequent studies.
- **Scalable Architecture**: Hosted on the Microsoft Azure Cloud, oomnia supports infinite trial scalability, ideally positioning Lumen for future studies. Our scalability ensures that Lumen will always have the most up to date version and latest features with regular pre-validated system updates.
- **Regulatory Compliance**: Built-in compliance with FDA 21 CFR Part 11, EU Annex 11, as well as GDPR and HIPAA compliance, oomnia features automated audit trails, electronic signatures, and secure data encryption—ensuring submission-ready datasets.

This unified approach minimizes manual processes, reduces errors, and accelerates timelines—advantages that competitors like Medidata or Veeva, with their modular add-ons, cannot match.

2.3. Benefits of the Wemedoo Approach

The approach used by Wemedoo in developing the oomnia unified clinical research system is a fundamental part of our culture of customer-centricity. Wemedoo is fiercely committed to efficiency, reducing redundancy and manual reconciliation, while always exceeding expectations.

The way we implement our solutions introduce downstream efficiencies that will result in dramatic time and total cost savings for the entire lifecycle of the trial. These include:

- **Reduced Manual Queries:** By implementing dynamic behavior in all but the initial questions in the CRF we will reduce manual query resolution between 33% and 66%. With 120 participants in the WT02 trial, this is expected to result in $50,000 - $100,000 savings in manual labor for query resolution by sites and trial monitors alone.
- **Optimal oomnia Workflows:** At Wemedoo we are the ultimate experts regarding the capabilities and use of our oomnia system. We will use that expertise to create the most efficient workflows for sites and investigators, thereby increasing their efficiency. This expertise will be used to ensure no unnecessary data is to be entered, and all data will be cleaned and validated upon entry.
- **Randomization within the eCRF:** By enabling direct randomization and allocation to treatment in the eCRF and tracking thereof we practically eliminate the reconciliation of randomization protocol deviations, and time spend manually tracking randomization, IMP supply and resupply.
- **Expert Device Integration:** Our Director of Integrations, with over 30 years of experience in the Australian healthcare system and clinical data integration will personally integrate the Horizon DXA and Withings Body Smart scale with oomnia and participant eCRFs. The integration will also enable oomnia to send notification to the Withings scale, thereby efficiently increasing participant compliance.
- **Implicit Training for Lumen:** By fully using our expertise and implementing our best practice workflows for which oomnia and our procedures we created, we will start to introduce the Lumen Bioscience team to our approach. This introduction with the preexisting expertise at Lumen will eventually enable the Lumen team to be equivalently efficacious as Wemedoo in the use of the oomnia system.

3. Study-by-Study Pricing Model: Flexibility at a Premium

The Study-by-Study (SBS) model is ideal for clients who need flexibility without committing to long-term agreements. Pricing is based on a per-study basis, with flat, predictable, monthly charges for each module selected.

3.1. One-Time oomnia Setup

The following are fees for work required to set up the oomnia unified clinical research system for a client. The **work** is not related to one specific study rather the entire oomnia system, and is performed only once for each client, regardless of how many trials will be performed in the future. The table below presents the associated setup costs including all integrations.

System	Initial Cost	Cost Per Subsequent Study
oomnia Core Installation *	$2,000*	N/A
ePRO/eConsent Installation *	$2,000*	N/A
Device API Implementation	$10,000/API	$3000/API
Withings Health Nudge Integration	$5000	$1500
CTMS Configuration *	$15,000*	N/A
TOTAL	**$44,000 ($19,000*)**	

** Fees waived for a commitment to oomnia system use for three or more SBS studies or Enterprise Model.*

For the oomnia Core (EDC, RTSM, eTMF, CTMS) and oomnia ePRO/eConsent installation, the following is included:

- Determination of server geolocation
- Custom oomnia instance installation with server specification
- Initial system configuration

For device API implementation, the following is included:

- Horizon DXA integration via API and/or HL7/FHIR protocols with automatic data transfer and association with individual participant eCRF data
- Implementation of the Withings API for automatic push transfer and association of data with individual participant eCRFs
- Data transfer testing and validation

Withings Health Nudge Integration

- Implementation of the Withings API for automatic push notification to participants' Withings Body Pro 2 scale. Health Nudges require the specific use of the Withings Body Pro 2 scale. If the Withings app allows for push notifications, it can also be used to notify participants.

Please note that, if required, any contracts or additional fees required by Withings or Horizon will be charged as a pass-through cost to Lumen Biosciences.

The first-time implementation of an API in the oomnia system has a flat fee and the APIs can be reused for subsequent studies. Once an API has been initially implemented it requires parameterization for each subsequent study to ensure it is connected to the new trial's organization structure, country, site, participant IDs, and the trial specific EDC documents. The work involved is approximately 30% of the initial work to set up the API.

3.2. SBS Module Pricing

Below are the monthly and total study lifetime costs for the complete oomnia Core unified clinical research system and the oomnia ePRO. Also presented are costs for the automatic data transfer from the Withings scale and Horizon DXA scanner directly to participants' eCRFs, thereby eliminating manual data transfer to sites/CRO, data entry, and subsequent reconciliation.

3.2.1. Monthly oomnia and API Costs for the WT02 Clinical Trial

Module	Description	Monthly Cost / Study	First Study Discount (20%)
EDC & RTSM	Data capture and stratified RTSM	$6,000	$4,800
eTMF	CDISC-TMF Reference model compliant	$800	$640
CTMS	Trial oversight, site management, milestones	$1,200	$960
ePRO	eDiary / Weekly Questionnaire	$1,450	$1160
Withings API	Bidirectional RESTful API to Withings medical cloud	$250	$200
Horizon DXA API	HL7/FHIR API for Hologic Horizon	$250	$200
Hosting & Data	Azure Cloud	Included*	Included *
Total		**$9,950**	**$7,960**

** Includes standard hosting plan on Microsoft Azure (HIPAA/GDPR compliant, with 99.99% uptime). Genomic and DICOM data are not included and will be charged separately.*

3.2.2. Total oomnia and API Costs for the WT02 Clinical Trial

The assumed duration of oomnia system use for the study will be from March 2025 to August 2026, a total of 18 months. The assumed system use will be broken down into study start-up, conduct, and close-out phases.

- 2 months study setup (March 2025 to April 2025)
- 12 months study conduct (May 2025 to April 2026)
- 4 months study closeout (May 2026 to August 2026)

- **Total Software Cost**: $143,280 ($7,960 × 18)

Discounts for commitment to oomnia system use for multiple SBS studies are available.

3.3. Optional Add-Ons for SBS Clients

24/7 Global Support $1200/month/study with a cap of $3600 per month for up to 12 studies.

3.4. Enterprise Pricing Model: Predictability and Cost Savings

The Enterprise Pricing Model is designed for organizations with multiple active studies or those planning long-term growth. By committing to a fixed 3-year term, Lumen gains access to the oomnia suite of capabilities at significantly reduced costs compared to Study-by-Study model pricing.

Key benefits of the Enterprise Pricing Model include:

- **Lower Software per Study Cost:** The enterprise model enables us to pass savings on to you, and to your investors.
- **Predictable Pricing:** Flat fees eliminate the unpredictability of SBS pricing when adding studies, while supporting multiple studies. A more predictable burn rate for investors.
- **Scalability:** Supports trials of any size or complexity without incremental costs, until reaching a predefined number of studies.
- **Waived CTMS Initial Configuration:** With the Enterprise Pricing Model and multi-study (three or more SBS) commitment, Wemedoo waives the fee for the initial configuration of the CTMS.

Wemedoo can create an Enterprise Pricing Model that works for you and your study pipeline.

3.5. No Hidden Costs: Growth Without Penalty

At Wemedoo, we believe in growing with our partners. That is why, regardless of pricing model (SBS or Enterprise), we do not charge for:

- **Added Sites:** Expand your trial footprint without worrying about incurring additional costs.
- **Increased Study Complexity:** Whether your trial involves adaptive designs or advanced analytics, your costs remain predictable.
- **Expanded Geography:** Go global without worrying about escalating fees.
- **More Subjects:** Enroll more participants without facing per-subject charges.

Additionally, we do not price based on study phase. Whether you're in Phase I or preparing for global Phase III studies, our pricing remains consistent. We grow when Lumen grows, and we win when Lumen begins its inevitable successful global Phase III studies.

4. Implementation Timelines

The following timelines are for illustrative purposes for a better understanding of the scope and sequence of the proposed work.

Timelines will be more accurately defined upon contract signature and protocol finalization.

4.1. Study Set-Up

The study setup will consist of four phases, including Pre-Implementation, Configuration and Study Instrument Setup, Validation, and Training and Go-Live. **Phase 1: Pre-Implementation (March 3 – 28, 2025)**

- Kick-off, Azure environment setup
- Trial module setup with roles and permissions
- EDC document design annotated with validation plans (CRF, SAE Report Form, PDL).
- TMF structure, TMF index, and access levels, TMF Plan Writing
- PRO instrument design
- CTMS planning and EDC document design with data validation (MVRs, logs, milestones, etc)
- DM and biostatistical protocol review

4.1.1. Phase 2: Configuration (17 March – April 18, 2025)

- EDC document implementation
- Study Data Standardization Plan

- RTSM implementation
- eTMF setup
- ePRO implementation
- DXA and Withings medical cloud API development
- CTMS Setup
- Randomization schedule and IMP supply kit list generation with documentation

4.1.2. Phase 3: Validation (March 31 – April 25, 2025)

- User Acceptance Testing (UAT)
  - EDC documents
  - eTMF
  - CTMS documents
  - RTSM
  - ePRO instruments
- Real-time report setup
- eCRF Validation Report and Data Management Plan writing
- Writing of study-specific training manuals

4.1.3. Phase 4: Training & Go-Live (April 28 – May 9, 2025)

- Site staff EDC, RTSM, eTMF, and ePRO
- Sponsor and CRO training
- First patient-in support

4.2. Study Conduct (May 2025 – April 2026)

- SDTM Annotated CRF creation
- Ongoing data review and data cleaning (EDC and ePRO)
- eTMF administration
- Support and administration
- Statistical Analysis Plan Writing
- Programming of statistical deliverables
- SDTM and ADaM dataset programming

4.3. Study Close Out (May 2026 – Aug 2026)

- MedDRA and ATC coding
- EDC database lock
- Finalization of statistical programming
- Finalization of SDTM and ADaM dataset programming
- Finalization of SDTM and ADaM Define.xml generation
- Statistical Analysis Report Writing
- Data transfer to sponsor/sites

5. Summary of Costs

Costs are separated into oomnia Core and oomnia ePRO licensing and hosting, installation, configuration and API integration, and Wemedoo Professional Services that are tailored to study requirements. The full suite of software and proposed services will ensure that the WT02 study will be set up on time, efficiently, and in manner which will reduce timelines and labor for Lumen Biosciences as well as the chosen CRO.

5.1. Oomnia Core and oomnia ePRO Licensing and Hosting Costs

The following software licensing and hosting assumes 18 months of system use, including setup, study conduct and close-out.

Category	Description	Cost (USD)
oomnia Core	Unified EDC, RTSM, eTMF, CTMS with Real-time Reports	$115,200.00
oomnia ePRO	oomnia ePRO	$20,880.00
API Maintenance	Horizon DXA and Withings Medical Cloud APIs	$7,200.00
TOTAL		**$143,280.00**

5.2. oomnia Core and ePRO Installation, Configuration and API Integration

The following assumes a commitment from Lumen Biosciences for oomnia system use for at least three (3) SBS studies or an Enterprise Pricing Model.

System	Description	Cost (USD)
oomnia Core Installation *	Custom oomnia instance installation with server specification and initial system configuration	Waived
ePRO/eConsent Installation *	Custom oomnia ePRO instance installation with server specification and initial system configuration	Waived
Horizon DXA API	HL7/FHIR API for Hologic Horizon	$10,000.00
Withings API Implementation	Withings HIPPA and GDPR compliant Medical Cloud integration	$10,000.00
Withings Health Nudge Integration	Implementation of push notifications from oomnia Core to the Withings Scale/App	$5000.00
CTMS Configuration *	Custom design and implementation of Lumen reports and dashboards	Waived
TOTAL		**$25,000.00**

5.3. Professional Services Costs

After our previous conversation:

- we revisited the rates of the professional services and reduced the hourly rates by approximately 28%
- ePRO associated services we added to more accurately represent the scope of work required to fulfil requirements of the WT02 protocol.

Service Category	Description	Estimated Cost (USD)
Data Management	EDC document design; trial, EDC document, RTSM, and real-time report setup; training; medical coding; database lock and transfer to sponsor/sites	$97,230.00
eTMF	CDISC-TMF Reference Model structure and eTMF index setup with access levels, limited eTMF administration, training, QC, finalization, export and transfer to sponsor	$32,230.00
ePRO	ePRO instrument design and implementation; real-time report setup, training and study specific user manuals, database lock	$48,954.80
Study Plan and Medical Writing	DM and biostatistical protocol review, eCRF Validation Report, DMP writing, TMF plan writing	$15,960.00
Biostatistics	Sample size, Randomization Schedule, IMP Kit number generation, Statistical Analysis Plan, TFL shells, statistical programming, Statistical Analysis Report	$59,360.00
CDISC Deliverables	Study Data Standardization Plan, SDTM annotated CRF, SDTM/ADaM datasets, SDTM and ADaM Define.xmls, SDTM/ADaM Reviewer's Guides, Preparation of data files for FDA submission	$113,196.00
Total Professional Services Cost	Total estimated costs as per the current understanding of the scope of work and the latest available draft protocol	**$366,930.80**

A breakdown of Wemedoo services, rate card, roles and responsibilities, study assumptions, and detailed breakdown of the activities included in each line item can be found in the excel file:

20250225_FIN_LMN-0801 RFP v1.2

This file is an integral part of the Wemedoo proposal for the WT02 clinical trial.

5.4. Summary of Costs

The total costs of all software, installation, API development, integration, and the Wemedoo award winning expert professional services (keys-in-hand) for the WT02 clinical trial are presented in the table below.

Description	Cost (USD)
Oomnia Core and oomnia ePRO Licensing and Hosting	$143,280.00
oomnia Core and ePRO Installation, Configuration, and API Integration	$25,000.00
Professional Services	$366,930.80
Grand Total	**$535,210.80**

6. Discounts Applied

6.1. Discounted Professional Service Rates

As per our previous conversation on Wednesday, February 25, 2025, we applied discounts to our professional service rates for the WT02 clinical trial.

For the sake of clarity, below you can see the discounted rates from the 20250130_FIN_LMN-0801 RFP v1.0.xlxs file.

The discounted rate card from the unit fees is follows:

Staff Role/Activity	Unit	Original Rate	Discounted Rate
Clinical Data Manager	Hour	200	150
Software Engineer	Hour	240	180
DM Project Manager	Hour	250	190
TMF Specialist	Hour	200	150
Medical Coder	Hour	200	150
Medical Writer	Hour	225	170
Quality Assurance Manager	Hour	200	160
Compliance/Legal	Hour	300	240
Biostatistician	Hour	240	170
Lead Biostatistician	Hour	230	190
Medical Monitor	Hour	300	240
Randomization Schedule	Schedule	7000	5000

The discounted rate for the CDISC deliverables is as follows:

Staff Role/Activity	Unit	Original Rate	Discounted Rate
SDTM Dataset Generation	Domain	1,125	900
SDTM Dataset Validation	Domain	725	580
SDTM Define.xml Generation	Domain	825	660
SDTM Define.xml Validation	Domain	195	156
Study Data Reviewers Guide	Domain	375	300
ADaM Dataset Generation	Domain	1,400	1,120
ADaM Dataset Validation	Domain	800	640
ADaM Define.xml Generation	Domain	1,300	1,040
ADaM Define.xml Validation	Domain	600	480
Analysis Data Reviewer's Guide	Domain	750	600
Preparation of data files for FDA Submission	Submission	8,000	6,000

Please note that for the benefit of Lumen Biopharma, we have added the Study Data Standardization Plan. The plan is highly recommended by the FDA and will be useful to Lumen when going forward with the LMN-0801 trial pipeline. It will allow for the standardization and reuse of study data across subsequent study phases.

6.2. Overall Discount

As requested, the new proposal for the WT02 study focuses only on the one WT02 clinical trial, therefore certain aspects of the original proposal have been updated, not only for the above rate cards, but for the services included, not limited to the addition of ePRO.

For the ease of understanding the differences, we present the cost summary by activity for the proposal as per the previous and new professional services rate cards.

Service Category	Previous WT02 Cost (USD)	New WT02 Cost (USD)	% Discount
Data Management	$132,916.67	$97,230.00	26.85%
eTMF	$42,633.33	$32,230.00	24.40%
ePRO	$64,281.47	$48,954.80	23.84%
Study Plan and Medical Writing	$21,080.00	$15,960.00	24.29%
Biostatistics	$81,190.00	$59,360.00	26.89%
CDISC Deliverables	$143,395.00	$113,196.00	21.06%
Total	**$485,496.47**	**$366,930.80**	**24.42%**

For complete transparency we are including following the excel file:

20250225_FIN_LMN-0801 RFP v1.2 for Discount Calculation.xlxs

The file is an exact representation of the new proposal of services, with the pre-discount rates.

6.3. Additional Rebate Incentive

At Wemedoo we are offering Lumen Biopharma additional discount in the form of a rebate incentive for future trials.

A **10% rebate** on each of the Wemedoo professional service categories used in the WT02 study will be credited toward each of the professional service categories for Lumen's next study with Wemedoo. Specifically:

Service Category	Estimated WT02 Cost (USD)	Future Rebate (USD)
Data Management	$97,230.00	$9,723.00
eTMF	$32,230.00	$3,230.00
ePRO	$48,954.80	$4,895.48
Study Plan and Medical Writing	$15,960.00	$1,596.00
Biostatistics	$59,360.00	$5,936.00
CDISC Deliverables	$113,196.00	$11,319.60
Total	**$366,930.80**	**$36,693.08**

The above rebate will be applied individually for each of the professional service categories in the above table, if they are used in Lumen's subsequent study with Wemedoo.

7. Payment Terms

7.1. Advance Payment

An advance payment of $131,760.00 equivalent to the following activities will be invoiced upon contract signature.

Oomnia Core and ePRO Installation, Configuration, and API Integration: $25,000

Oomnia Core and ePRO Licensing and Hosting during study Set-Up: $15,920

Data and Project Management: $47,470

- Trial setup: $900
- Clinical Database organization and Administration: $1,650
- eCRF Design and Implementation: $23,720
- eSAE Report Form Design and Implementation: $6,000
- electronic Protocol Deviation Log Form Design and Implementation: $6,900
- RTM Setup: $8,300

eTMF Setup and Administration: $5,420

- eTMF Folder Structure Setup: $3,900
- eTMF Administration During Study Start-Up: $1,520

ePRO Instrument Design and Implementation: $17,040

- Daily eDiary Design: $1,200
- Daily eDiary Review: $570
- Implementation of Daily eDiary: $600
- Implementation of Automatic Reminders and Scheduler for Daily eDiary: $4,800
- Daily eDiary Testing / Validation and Documentation: $1,200
- Weekly Questionnaire Design: $1,800
- Weekly Questionnaire Review: $570
- Implementation of Weekly Questionnaire: $900
- Implementation of Automatic Reminders and Scheduler for Weekly Questionnaire: $3,600
- Weekly Questionnaire eDiary Testing / Validation and Documentation: $1,800

Study Plan and Medical Writing: $4,560

- Biostatistical protocol review: $2,280
- Data management protocol review: $2,280

Biostatistical Services: $8,740

- Sample Size Calculation and Documentation: $2,720
- Randomization Schedule Generation and Documentation: $5,000
- IMP Kit Number Generation and Documentation: $1,020

CDISC Deliverables: $7,520

- Study Data Standardization Plan: $7,520

7.2. Payment Schedule

A full payment schedule will be presented upon signing of the contract, however for clarity the following are assumed and will be:

- **Software**: $7,960/month for 16 months, after the first two months after the initiation of use of the software. The number of months that software licensing and hosting fees are charged may decrease or increase due to shortening or extending study duration due to faster or slower recruitment.
- **Professional Services**: Billed monthly only upon completion.

8. Conclusion

This proposal is designed to align with Lumen's vision, offering a seamless, cost-effective solution to accelerate your groundbreaking therapies while keeping the costs and payments predictable.

9. Next Steps

The final pricing and terms will be agreed between Wemedoo and Lumen Biosciences. The agreement will be detailed in the **Order Form** and attached to the **Software as a Service** and **Master Services Agreements**.