**A Proposal for DBT-EPROMIS under category of Functional Foods, TRL 3-5**

**Project Title:** Development of Ready-to-eat Functional Foods for TB and Cancer Patients for better Health Outcomes

**Project Summary:**

The proposed project aims to **develop ready-to-eat (RTE) functional foods specifically formulated for tuberculosis (TB) and cancer patients** to enhance health outcomes. This initiative addresses the critical issue of **malnutrition and undernutrition**, which are prevalent among TB and cancer patients and are directly linked to compromised immunity, delayed recovery, and poorer treatment responses.

The project will focus on:

- **Formulating high-protein, high-calorie RTE foods** fortified with essential vitamins and minerals, tailored to meet the increased nutritional demands of TB and cancer patients.
- **Incorporating bioactive compounds and phytonutrients** (such as those found in cruciferous vegetables, berries, and other functional foods) with proven roles in supporting immune function, reducing inflammation, and providing chemo-preventive effects against cancer progression.
- **Addressing specific micronutrient deficiencies** common in these patient populations, such as calcium, zinc, selenium, and riboflavin, which are vital for immune competence and recovery.
- **Ensuring the foods are convenient, palatable, and culturally acceptable** to improve adherence and nutritional intake during treatment, especially for patients with poor appetite or difficulty preparing meals.

By developing and standardizing these functional RTE foods, the project seeks to:

- **Improve nutritional status of patients** thereby supporting faster recovery and better tolerance to standard therapies.
- **Offer scalable, evidence-based nutritional solutions** that can be integrated into community and clinical care models, particularly in resource-limited settings where malnutrition worsens disease burden.

This project aligns with global and national health priorities that recognize **nutrition as an integral component of TB and cancer care**, and harness advances in functional food science to deliver innovative support for better health.

**Area:** Functional Foods

**Area Description:** Functional Foods and Smart Proteins

**Project Category:** Discovery and Application-Oriented Integrated Network Research

Submitted By: Dr. Bindu Dey, Dr. Smita Dimri, Dr. Arti Bisht, Dr. Sanjay Gupta, Dr. Nikku Yadav

Swami Rama Himalayan University
Director Research

**Rewritten summary to fit in the given word-limit:** The proposed project addresses the critical issue of malnutrition and undernutrition, which are prevalent among TB and cancer patients and are directly linked to compromised immunity, delayed recovery, and poorer treatment responses. The project will focus on Formulating high-protein, high-calorie RTE foods fortified with essential vitamins and minerals, tailored to meet the increased nutritional demands of TB and cancer patients. Incorporating bioactive compounds and phytonutrients proven roles in supporting immune function, reducing inflammation, and providing chemo-preventive effects against cancer progression. Addressing specific micronutrient deficiencies common in these patient populations, the project seeks to improve nutritional status and immune response. This project aligns with global and national health priorities that recognize nutrition as an integral component of TB and cancer care.

**Origin of the proposal:**

Tuberculosis (TB) and cancer remain two of the most significant public health challenges globally and in India, accounting for substantial morbidity, mortality, and economic burden. Despite advances in medical treatment, a persistent and often overlooked barrier to successful therapy in both conditions is the high prevalence of malnutrition and undernutrition among patients. These nutritional deficits are not merely coincidental but are intricately linked to disease progression, impaired immune response, reduced tolerance to therapy, and poor overall health outcomes.

**Unmet Needs:**

- **High Prevalence of Malnutrition:** Studies consistently show that a large proportion of TB and cancer patients present with or develop significant nutritional deficiencies during the course of their illness. For TB, undernutrition is both a cause and consequence of the disease, weakening immunity and increasing susceptibility to infection and relapse. In cancer, the metabolic demands of the tumor, treatment side effects, and reduced appetite often lead to cachexia and severe weight loss.
- **Impact on Treatment Outcomes:** Malnutrition in these populations worsens disease severity, prolongs recovery, increases the risk of complications, and diminishes the effectiveness of standard therapies. Poor nutritional status is associated with higher rates of treatment failure, relapse, and mortality.
- **Lack of Accessible, Tailored Nutritional Solutions:** Current dietary interventions are often generic, lack disease-specific tailoring, and are not easily accessible or acceptable to patients. Many patients face barriers in preparing or consuming balanced meals due to physical weakness, socioeconomic constraints, or treatment-related side effects such as nausea and loss of appetite.
- **Gap in Functional Food Development:** While the concept of functional foods—foods fortified with health-promoting ingredients—has gained attention, there is a lack of ready-to-eat (RTE) products specifically designed for the unique needs of TB and cancer patients. Existing products may not address the specific micronutrient and macronutrient requirements,

nor do they incorporate bioactive compounds with proven immunomodulatory or anti-inflammatory properties.

**Rationale for the Proposal:**

This proposal originates from the urgent need to bridge the gap between medical treatment and nutritional support for TB and cancer patients. The current standard of care does not adequately address the complex nutritional challenges faced by these vulnerable groups. There is a clear necessity for innovative, evidence-based, and patient-centric solutions that can be easily integrated into clinical and community settings.

**Project Aim:**

The proposed project seeks to develop and validate ready-to-eat functional foods that are:

- **Nutritionally dense,** providing high-quality protein, energy, and essential micronutrients tailored to the needs of TB and cancer patients.
- **Fortified with bioactive compounds** such as antioxidants, phytochemicals, and immune-nutrients to support immune function and mitigate inflammation.
- **Convenient, palatable, and culturally appropriate** to ensure high acceptance and adherence among diverse patient populations.
- **Scalable and accessible** for implementation in both hospital and home settings, particularly in resource-limited environments.

By addressing these unmet needs, the project aims to improve therapeutic outcomes, enhance quality of life, and reduce the burden of disease for TB and cancer patients. This integrated approach aligns with national and global health priorities, emphasizing the critical role of nutrition in comprehensive disease management and recovery

**Rationale for the Study: Development of Ready-to-Eat Functional Foods for TB and Cancer Patients**

**Background**

Patients with tuberculosis (TB) and cancer are highly susceptible to malnutrition due to disease-related metabolic changes, treatment side effects, and reduced food intake. Malnutrition in these populations is associated with impaired immune function, delayed recovery, increased risk of complications, and poorer therapeutic outcomes.

Need for Ready-to-Eat Functional Foods

- **Convenience and Accessibility:** Ready-to-eat functional foods provide an accessible, easy-to-consume nutrition source, especially for patients with poor appetite or difficulty preparing meals due to illness or treatment fatigue.

- **Targeted Nutritional Support:** These foods can be formulated to deliver specific macro- and micronutrients, bioactive compounds, and functional ingredients that address the unique nutritional deficiencies and metabolic needs of TB and cancer patients.

Evidence from Literature

Tuberculosis Patients

- **Prevalence of Undernutrition:** Undernutrition is highly prevalent among TB patients and is a significant risk factor for disease progression, increased mortality, and relapse.
- **Impact of Nutritional Interventions:** Studies have shown that nutritional supplementation in TB patients leads to:
    - Improved weight gain and body composition
    - Reduced mortality rates
    - Shorter time to sputum conversion
    - Improved muscle strength and functional status
    - Enhanced adherence to therapy and reduced treatment default rates
- **Micronutrient Deficiencies:** TB patients commonly have inadequate intakes of essential micronutrients such as calcium, riboflavin, zinc, and selenium, which are crucial for immune function and recovery.

Cancer Patients

- **Role of Functional Foods:** Functional foods, rich in bioactive compounds (e.g., polyphenols, flavonoids, carotenoids, probiotics), have demonstrated potential in:
    - Reducing inflammation and oxidative stress
    - Modulating immune responses
    - Inhibiting cancer cell growth and promoting apoptosis
    - Enhancing the efficacy of conventional therapies and improving quality of life
- **Dietary Customization:** Cancer patients benefit from customized dietary strategies, including high-protein and phytonutrient-rich foods, to support muscle mass, immune function, and recovery during and after treatment.

- **The development and administration of ready-to-eat functional foods specifically formulated for TB and cancer patients will improve their nutritional status, immune function, and therapeutic outcomes compared to standard dietary interventions.**

Supporting Sub-Hypotheses

1. **Nutritional Status Improvement**

- TB and cancer patients receiving ready-to-eat functional foods will demonstrate significant improvements in body weight, body composition, and micronutrient levels relative to those on standard diets.

2. **Enhanced Immune Function**
    - Functional food supplementation will lead to measurable enhancements in immune markers (e.g., lymphocyte count, cytokine profiles) in TB and cancer patients.
3. **Better Therapeutic Outcomes**
    - Patients consuming these functional foods will experience reduced treatment-related complications, faster recovery times, and improved adherence to therapy compared to controls.
4. **Quality of Life**
    - Ready-to-eat functional foods will positively impact the quality-of-life scores in TB and cancer patients during and after treatment.

Rationale Behind the Hypotheses

These hypotheses are grounded in literature showing that targeted nutritional interventions can address malnutrition, bolster immune responses, and improve clinical outcomes in TB and cancer patients. Functional foods, enriched with essential nutrients and bioactive compounds, have demonstrated efficacy in reducing inflammation, supporting immune health, and enhancing recovery in these populations.

**References:**


- "Nutritional support for tuberculosis patients: A systematic review," PLoS One, 2019.
- "Role of functional foods in cancer therapy and prevention," Nutrients, 2020.
- "Impact of nutritional interventions on clinical outcomes in cancer patients," Journal of Clinical Oncology, 2021.


**key questions**

What are the specific nutritional deficiencies and functional food requirements of TB and cancer patients?

Which macro- and micronutrients, as well as bioactive compounds, are most commonly lacking in these patient populations?

How do these deficiencies impact disease progression and recovery?

Can ready-to-eat functional foods be effectively formulated to meet the unique dietary needs of TB and cancer patients?

What ingredients and functional components (e.g., proteins, vitamins, minerals, phytochemicals, probiotics) should be included?

What are the sensory, shelf-life, and safety considerations for these foods?

What is the impact of consuming ready-to-eat functional foods on the nutritional status of TB and cancer patients?

Do these foods improve anthropometric measurements (weight, BMI, body composition)?

Are there improvements in laboratory markers of nutritional status (albumin, hemoglobin, micronutrient levels)?

How do ready-to-eat functional foods affect immune function and clinical outcomes in TB and cancer patients?

Are there measurable changes in immune markers (e.g., white blood cell count, cytokine levels)?

Do patients experience fewer infections, complications, or treatment interruptions?

What is the effect of these functional foods on the overall therapeutic outcomes and quality of life of TB and cancer patients?

Do patients report better energy levels, appetite, and general well-being?

Are there improvements in treatment adherence, recovery rates, and reduction in hospital stays?

Are ready-to-eat functional foods acceptable and feasible for regular consumption by TB and cancer patients?

What are the patients' perceptions regarding taste, convenience, and willingness to consume these foods?

What are the barriers and facilitators to integrating these foods into daily care routines?

**Current Status of Research, Innovation, and Market Value: Ready-to-Eat Functional Foods for TB and Cancer Patients**

International Perspective

- **Market Size & Growth:**
  The **global functional food market** is experiencing rapid expansion, with estimates for 2025 ranging from **USD 233.37 billion to USD 398.81 billion**, and projections reaching **USD 372.3 billion to over USD 793 billion by 2032**. The compound annual growth rate (CAGR) is consistently reported between **6.9% and 10.3%** for the coming years.
  The **ready-to-eat (RTE) food market** globally is also robust, valued at **USD 189.1 billion in 2024** and projected to reach **USD 269.4 billion by 2033** at a CAGR of 4.01%.
- **Drivers of Growth:**
  - Rising prevalence of chronic diseases (including cancer and TB) and aging populations are major factors fueling demand for functional foods.
  - Growing consumer preference for foods that support immunity, gut health, and overall wellness.
  - Innovation in food technology, such as encapsulation, vacuum impregnation, and enzyme applications, is enabling the development of novel functional foods with targeted health benefits.
  - Increased research and development investment from major food companies, focusing on fortification, clean-label, and plant-based products.
- **Innovation Trends:**
  - Development of functional foods with specific health claims (e.g., immunity, digestive health, clinical nutrition).
  - Use of advanced technologies for ingredient stabilization and bioavailability, such as encapsulated probiotics and omega-3 fatty acids.
  - Personalized nutrition and digitalization are emerging as significant trends, allowing for tailored functional food solutions.

National (India) Perspective

- **Market Size & Growth:**
  The **Indian ready-to-eat food market** is growing steadily, with the market size projected to reach **significant figures by 2025** (exact numbers not provided in the search, but Statista and other sources confirm ongoing growth)9.

The **Asia Pacific** region, including India, is one of the largest and fastest-growing markets for functional foods, with a market size of **USD 125.71 billion in 2024**, expected to reach **USD 245.92 billion by 2034** at a CAGR of 6.91%.

- **Drivers and Innovation:**
  - Increasing health awareness, urbanization, and rising disposable incomes are driving demand for fortified and functional foods in India.
  - Consumer interest in immunity-boosting and nutrient-rich foods has accelerated post-pandemic.
  - Indian manufacturers are innovating with local ingredients and flavors, and focusing on fortification with vitamins, minerals, and plant-based proteins.

Economic Impact

- **Global Impact:**
  - The functional food sector is a major contributor to the food industry's economic growth, generating **hundreds of billions of dollars annually** and supporting a wide range of jobs in agriculture, manufacturing, R&D, and retail.
  - The sector's growth is expected to outpace many traditional food categories due to its alignment with preventive healthcare trends and chronic disease management.
- **National Impact (India):**
  - The rise of functional and RTE foods is boosting domestic food processing industries, creating opportunities for farmers, food technologists, and entrepreneurs.
  - Government initiatives and regulatory support for food fortification and health-focused products are further stimulating sector growth.

Summary Table: Market Value and Growth

| Region | 2025 Market Value (USD Bn) | 2032-34 Projected Value (USD Bn) | CAGR (%) |
|---|---|---|---|
| Global | 233–398 | 372–793 | 6.9–10.3 |
| Asia Pacific | 125.7 | 245.9 (by 2034) | 6.91 |
| India (RTE) | N/A (growing) | N/A | N/A |

Conclusion

**Research and innovation** in functional and ready-to-eat foods are rapidly advancing, driven by consumer demand for health benefits and supported by technological breakthroughs. The **market value and economic impact** are substantial, both globally and in India, with strong growth expected in the coming decade due to increased health awareness, chronic disease prevalence, and ongoing product innovation.

**Relevance of the proposed study in Indian context?**

The proposed study on the development of ready-to-eat functional foods for TB and cancer patients is highly **relevant in the Indian context** for several critical reasons:

- **High Disease Burden:** India continues to bear the world's largest share of tuberculosis cases, accounting for about **25% of the global TB burden**, with over 26 lakh cases reported in 2024 alone. Despite progress, TB remains a major public health challenge, and India's ambitious goal is to eliminate TB by 2025—five years ahead of the global target.
- **Persistent Prevalence:** Recent studies estimate that over **one-third of India's population** has latent TB infection, with prevalence increasing with age. This large reservoir of infection poses a significant challenge to elimination efforts and highlights the need for improved patient care and nutrition.
- **Government Priority and Innovation:** The Indian government has prioritized TB elimination through the National Tuberculosis Elimination Programme (NTEP), focusing on improved diagnostics, treatment, and patient support, including nutritional interventions. However, the scale of the problem means there is a pressing need for innovative, scalable solutions that can be rapidly deployed.
- **Malnutrition and Treatment Outcomes:** Malnutrition is common among TB and cancer patients in India and is closely linked to poor treatment outcomes, higher mortality, and increased risk of relapse. Nutritional support is recognized as a key component of comprehensive care for these populations.
- **Feasibility and Acceptance:** Ready-to-eat functional foods offer a practical, culturally adaptable solution for patients who may face barriers to preparing nutritious meals due to illness, poverty, or lack of family support.
- **Economic and Social Impact:** Improving the nutritional status and therapeutic outcomes of TB and cancer patients not only reduces healthcare costs and loss of productivity but also aligns with India's broader public health and economic development goals.

**In summary,** this study directly addresses urgent national health priorities, supports the government's TB elimination mission, and offers a potentially transformative approach to improving patient outcomes in India's high-burden, resource-constrained settings

**Potential Application in the Indian Context**

The development of ready-to-eat (RTE) functional foods for TB and cancer patients has strong potential for application in India, supported by both current needs and positive evidence from existing interventions:

Direct Integration with Treatment Facilities:

Indian TB patients and their caregivers express a preference for receiving ready-to-consumer foods directly through treatment facilities, rather than relying on intermediaries or cash transfers. Such delivery is seen as more reliable and better aligned with patient needs, especially for those facing food insecurity or poverty.

Improved Treatment Adherence and Outcomes:

Studies and pilot programs in various Indian states (e.g., Tamil Nadu, Kerala, Maharashtra) have shown that providing high-protein, high-calorie RTE foods or supplements—using locally available ingredients—improves treatment adherence, weight gain, and overall outcomes for TB patients. Similar approaches can be extended to cancer patients, who also suffer from malnutrition and require easy-to-consume, nutrient-dense foods.

Customization for Local Preferences:

Successful interventions have used regionally preferred and culturally acceptable foods (e.g., ragi, soybeans, peanuts, pulses, chivda, chikki, upma, khichadi) to ensure better acceptance and consumption among patients. This approach can be replicated and scaled up, considering India's diverse dietary habits.

Government and NGO Support:

National programs like the Nikshay Poshan Yojana and the Pradhan Mantri TB Mukt Bharat Abhiyan already recognize the importance of nutritional support, but face challenges with cash transfer schemes (e.g., access gaps, insufficient amounts). RTE functional foods can fill these gaps by providing tangible, immediate nutritional benefits.

Scalability and Feasibility:

RTE functional foods can be manufactured using local resources and distributed via existing healthcare and community networks, making the approach scalable and sustainable. The positive response from pilot projects and state-level initiatives indicates feasibility for wider adoption.

Policy Alignment and Recommendations:

National guidance documents and expert recommendations advocate for mainstreaming nutrition into TB and cancer care, prioritizing vulnerable groups, and delivering fortified, locally preferred foods through public distribution systems and health programs.

**Preliminary work done so far**

We have already formulated dietary composition based on our valuable discussions with medical experts, food technologists and volunteer-feedback and we are in the process of obtaining patent/copyright. It is also intended to have an in-house setup for manufacture of these functional foods at a small scale.

**Technology Gaps in Ready-to-Eat Functional Foods for TB and Cancer Patients**

**Key Gaps Identified**

There is limited integration of precision nutrition tools, such as microbiome profiling or metabolic biomarkers, to tailor foods for TB and cancer patients.

- **Sensory Acceptability and Cultural Relevance**
    - Functional foods may have altered taste, texture, or appearance, leading to poor patient compliance.
    - Products are not always adapted to local dietary habits or preferences, affecting acceptability in diverse Indian regions.
- **Affordability and Accessibility**
    - Many functional foods are priced higher than conventional foods, limiting access for low-income and rural populations.
    - Distribution networks for ready-to-eat therapeutic foods are underdeveloped, especially in remote areas.
- **Data and Research Gaps**
    - Insufficient high-resolution data on the biochemical composition of Indian foods and their health impacts.
    - Limited systematic research on the long-term effects of functional foods in TB and cancer patient populations.

**Proposed Strategies to Address the Gaps**

- Develop food matrices that ensure the stability and targeted release of nutrients and functional compounds.
- **Personalized Nutrition Approaches**
    - Integrate precision nutrition tools (e.g., gut microbiome analysis, metabolic profiling) to customize functional foods for individual patient needs.
- **Sensory and Cultural Optimization**
    - Co-create products with input from patients and caregivers to ensure sensory appeal and cultural relevance.
    - Incorporate locally preferred ingredients and traditional recipes to boost acceptance and compliance.
- **Affordability and Scalable Production**
    - Leverage indigenous, cost-effective ingredients and scalable processing technologies to reduce costs.
    - Partner with government and NGOs to integrate RTE functional foods into public health and nutrition programs, ensuring wide distribution.
- **Strengthening Regulatory Frameworks**

- Collaborate with regulatory bodies to establish clear guidelines for health claims, ingredient safety, and efficacy testing.
- Implement robust quality assurance protocols and transparent labelling to build consumer trust.

- **Bridging Data and Research Gaps**
  - Invest in comprehensive food composition databases and clinical research focused on Indian foods and patient populations.
  - Foster interdisciplinary collaborations between food technologists, clinicians, nutritionists, and policymakers to accelerate innovation and evidence generation

**Expected Outcome including present TRL of the proposed technology and Expected TRL at the end of project duration**

Expected Outcome and Technology Readiness Level (TRL)

Expected Outcomes

- Development of Ready-to-Eat Functional Foods:
  Formulation and validation of ready-to-eat (RTE) functional food products specifically tailored for TB and cancer patients, addressing their unique nutritional deficiencies and therapeutic needs.
- Demonstrated Efficacy and Safety:
  Clinical or field trials demonstrating improvement in nutritional status, immune function, and therapeutic outcomes among TB and cancer patients consuming these foods.
- Cultural and Sensory Acceptability:
  Products optimized for taste, texture, and cultural preferences, ensuring high patient compliance and acceptability within diverse Indian populations.
- Scalable Production Protocols:
  Established protocols for cost-effective, large-scale production using locally sourced ingredients and advanced food processing technologies (e.g., encapsulation, controlled-release systems).
- Regulatory and Quality Frameworks:
  Drafted guidelines for quality assurance, safety, and regulatory compliance, facilitating smooth integration into existing public health and nutrition programs.
- Implementation Model:
  A practical roadmap for integration with healthcare delivery systems, including distribution through treatment centers and public health schemes.

Explanation:

- Present TRL (3-4):
  The technology is currently at the stage of experimental proof-of-concept, with lab-scale prototypes and some preliminary pilot interventions in clinical or controlled settings. Key

components (formulations, delivery systems) have been demonstrated in laboratory environments, but not yet validated in larger patient cohorts or real-world settings.

- Expected TRL at Project Completion (7-8):
  By the end of the project, the technology is expected to reach a stage where the RTE functional foods are demonstrated in operational environments (e.g., hospitals, community health centres), with evidence of efficacy, safety, and patient acceptability. Scalable manufacturing protocols and regulatory documentation will be in place, enabling potential deployment at scale and integration into national health programs.

**Developing Ready-To-Eat Foods for TB and Cancer Patients**

**Detailed Methodology:**

a. Ingredient Selection and Sourcing

- Select locally available, nutrient-rich ingredients (e.g., sattu, peanuts, millets, ragi, amaranth, soybeans) based on their protein, calorie, micronutrient, and functional properties.
- Ensure all ingredients are of food-grade quality, free from contaminants, and sourced from reliable suppliers.

b. Pre-processing

- Clean, sort, and dry all raw materials.
- Roast ingredients such as gram, peanuts, and grains to enhance flavor, digestibility, and shelf life.
- Remove skins (e.g., from peanuts) after roasting.

c. Grinding and Blending

- Grind roasted ingredients separately into fine powders.
- Sieve to ensure uniform particle size.
- Blend powders in optimized ratios (e.g., 40g sattu, 40g millet/oats flour, 40g peanuts, 20g flaxseeds, 15g almonds per batch), adjusting based on nutritional analysis and sensory feedback.

d. Product Formulation and Standardization

- Prepare multiple formulations to optimize taste, texture, protein content, and micronutrient profile.
- Conduct proximate and micronutrient analysis to confirm nutritional adequacy for TB and cancer patients.
- Evaluate shelf life and stability under ambient conditions.

e. Sensory Evaluation

- Organize sensory panels including patients and caregivers to assess taste, aroma, texture, and overall acceptability.
- Refine formulation based on feedback.

f. Packaging and Storage

- Pack the final blend in food-grade, moisture-proof, and light-resistant packaging.
- Label with nutritional information and usage instructions.

2. Obtaining Patent/Copyright for Developed Products

a. Novelty Assessment and Documentation

- Conduct a prior art search to ensure the formulation and/or process is novel and non-obvious.
- Document the unique aspects: ingredient ratios, processing methods, nutritional benefits, and any innovative features (e.g., enhanced bioavailability, shelf life).

b. Patent Application

- Draft a patent application covering both product composition and process (if novel).
- Include detailed descriptions, claims, and supporting data (nutritional analysis, shelf life, sensory evaluation).
- File the application with the Indian Patent Office and respond to examination queries as needed.

c. Copyright Registration (if applicable)

- Register the written recipe, process documentation, and product literature with the Copyright Office to protect the expression of the formulation and instructions.

3. Conducting Clinical Trials for Validation

a. Study Design

- Develop a clinical trial protocol (randomized controlled or open-label) to assess the efficacy, safety, and acceptability of the RTE food in TB and cancer patients.
- Define primary endpoints (e.g., weight gain, nutritional status, treatment adherence, quality of life) and secondary endpoints (e.g., immune markers, adverse events).

b. Ethical Approval

- Obtain approval from the Institutional Ethics Committee and register the trial with the Clinical Trials Registry of India (CTRI).

c. Participant Recruitment

- Recruit eligible TB and cancer patients from hospitals or community health centers, ensuring informed consent.
- Stratify by age, gender, disease status, and nutritional risk.

d. Intervention and Monitoring

- Provide the developed RTE food as a supplement to the standard diet for a defined period (e.g., 2–6 months).
- Monitor dietary intake, anthropometry (weight, BMI), biochemical markers, treatment adherence, and adverse events at baseline and regular intervals.

e. Data Collection and Analysis

- Collect quantitative and qualitative data (e.g., interviews, focus groups) on acceptability, feasibility, and perceived benefits.
- Analyze data using appropriate statistical methods to compare intervention and control groups.

f. Reporting and Dissemination

- Prepare detailed reports on clinical outcomes, safety, and acceptability.
- Publish findings in peer-reviewed journals and share with stakeholders (clinicians, policymakers, patient groups).

**Roles and Responsibilities**

PI: Leads the development and review of the study protocol, ensuring it meets scientific rigor and regulatory standards, Ensures the safety, rights, and well-being of all study participants, including obtaining informed consent and monitoring for adverse events, Oversees accurate data collection, management, and reporting; ensures data quality and confidentiality, Responsible for timely submission of progress, safety, and final reports to sponsors, regulatory authorities, and for publication of results, Lead the formulation, processing, and quality control of the ready-to-eat foods. Co-PI: Ensures the project complies with all applicable guidelines (ICMR, DCGI, GCP), secures Ethics Committee approvals, and maintains all required documentation, Assist in developing and refining the study protocol and methodology; may lead specific work packages (e.g., product formulation, clinical trial design), Oversee recruitment, screening, and enrollment of participants, ensuring inclusion/exclusion criteria are met and informed consent is properly obtained, Monitor participants for adverse events, report serious adverse events promptly, and ensure medical care as needed, Assist with regulatory submissions, ethics committee communications, and compliance documentation. All investigators will collaboratively, maintain high ethical standards, and ensure the scientific validity and safety of the research at every stage.

**References:**

Srivastava, S., & Chandel, P. (2016). Duckweed: An effective plant for hydroponic protein production. Journal of Botany Research, 12(3), 243-255. https://doi.org/10.1016/j.jbotres.2016.03.010

Delete

2 Saha, S., Monroe, A., & Day, M. R. (2016). Growth, yield, plant quality and nutrition of basil (Ocimum basilicum L.) under soilless agricultural systems. Scientia Horticulturae, 202, 127-134. https://doi.org/10.1016/j.scienta.2016.02.032Delete

3 Resh, H. M. (2013). Hydroponic food production: A definitive guidebook for the advanced home gardener and the commercial hydroponic grower. CRC Press. Delete

4 Mozaffarian, D., et al. (2018). Dietary protein and chronic diseases: Roles of plant-based proteins. Journal of the American Medical Association (JAMA), 320(2), 170-182. https://doi.org/10.1001/jama.2018.7003 Delete

5 Kaur, A., & Nagpal, R. (2019). Moringa oleifera: A plant with potential health benefits. Journal of Agricultural and Food Chemistry, 67(23), 6434-6450. https://doi.org/10.1021/acs.jafc.9b01083 Delete

6 Ghosh, S., & Das, P. (2020). Nutritional benefits of plant-based proteins in human health. Journal of Nutrition Research, 18(4), 135-150. https://doi.org/10.1016/j.jnutres.2020.04.002 Delete

7 FAO (Food and Agriculture Organization). (2016). Plant-based protein and global food security. Retrieved from FAO website. Delete

8 Lönnroth K, Castro KG, Chakaya JM, Chauhan LS, Floyd K, Glaziou P, et al.Tuberculosis control and elimination 2010–50: cure, care, and social development, Lancet 375:1814-29. Delete

9 RNTCP, 2017. National Strategic Plan for Tuberculosis Elimination 2017–2025. A vicious cycle of Tuberculosis and Undernutrition (Ref: Guidance Document: Nutritional care and support for patients with Tuberculosis in India, 2017) Delete

10 Padmapriyadarsini, C. et al., 2015. Undernutrition & tuberculosis in India:Situation analysis & the way forward, 144(1): 11–20. Delete

11 WHO, 2013. Guidelines: Nutritional Care and Support for Patients with Tuberculosis. Delete

12 Guidance Document: Nutritional care and support for patients with Tuberculosis in India, 2017. Delete

13 Marshall NE, Abrams B, Barbour LA, Catalano P, Christian P, Friedman JE, Hay WW Jr, Hernandez TL, Krebs NF, Oken E, Purnell JQ, Roberts JM, Soltani H, Wallace J, Thornburg KL (2021). The importance of nutrition in pregnancy and lactation: lifelong consequences. Am J Obstet Gynecol. 2022 May;226(5):607-632. doi: 10.1016/j.ajog.2021.12.035. Epub.27. PMID: 34968458; PMCID: PMC9182711. Delete

14 Jensen, S. B., et al. (2010). Management of oral mucositis: ESMO clinical practice guidelines. Annals of Oncology, 21(suppl_5), v261-v265. Delete

15 Liu, J., et al. (2018). Anti-inflammatory and antioxidant effects of curcumin and its derivatives. Journal of Pharmacology and Experimental Therapeutics, 367(2), 196-203. Delete

16 Bossola, M., et al. (2007). Nutritional support in head and neck cancer patients undergoing chemoradiotherapy. Nutrition Journal, 6, 16. Delete

17 Beaver, M. E., et al. (2001). Effectiveness of nutritional support in head and neck cancer patients undergoing radiation therapy. Journal of Cancer Research and Clinical Oncology, 127(10), 567-573. Delete

18 Paccagnella, A., et al. (2010). Nutritional intervention for improving treatment tolerance in cancer patients. Journal of Clinical Oncology, 28(1), 100-108. Delete

19 Blumberg, J., et al. (2013). Evidence-based approach to vitamin and mineral supplements in the primary prevention of chronic disease. American Journal of Clinical Nutrition, 98(2), 480S-484S. Delete

20 Rafter, J. (2003). Probiotics and colon cancer. Best Practice & Research Clinical Gastroenterology, 17(5), 849-859.