Indian Solution to Global Health Problems via Globally Patented New Immunity Drugs:NID (Radha 108 & Secretion of Biosimilars)



Dr. Pawan Saharan MS
PHD(USA)
drpawan@biomix.in, www.biomix.in

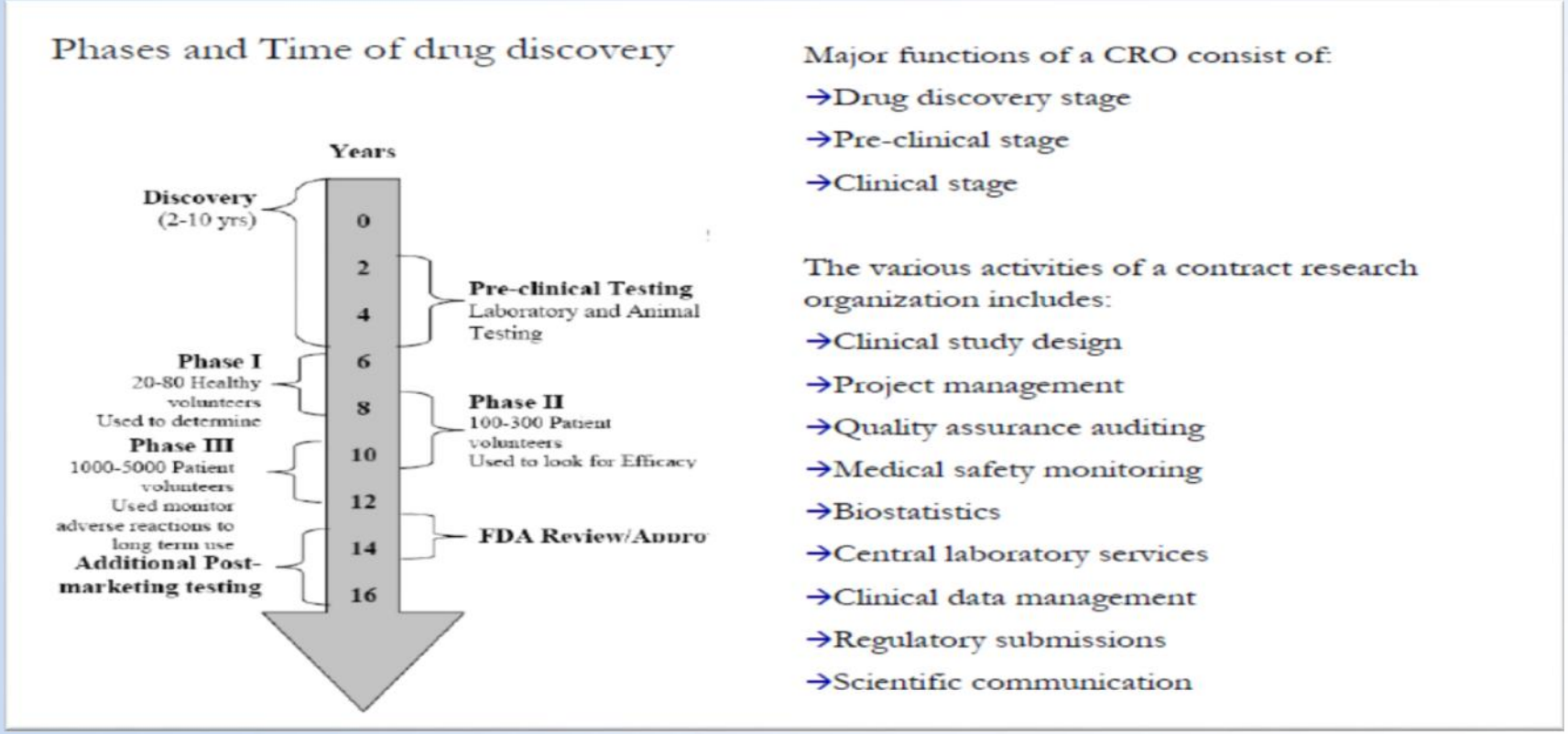
Innovation Journey of New Immunity Drug (NID)

- Dr. George Wald, Nobel laureate & Prof. Joseph Weizenbaum, father of artificial intelligence at MIT, USA brain stormed with the Biomix team.
- Poor Immunity was found to be the #1 reason for majority of diseases.
- Several immunity drugs existed, however none could ; "build body's own immunity like mother's first milk". This was the insight & lead for the research team.
- After 10 years of research , we have successfully isolated Nanopeptides from bovine colostrum and conducted global clinical studies on 30000 patients suffering from communicable disease and Immune disorders via innovative oral spray drug delivery system.
- Radha 108 which also produces Biosimilars like IL, IFN & TNF, at the most affordable price creating a paradigm shift in the pharmaceutical speciality and generic industry.

Creating paradigm shift in health care from ' Prevention to Cure'

Fleming discovered Penicillin G, which saved millions from bacterial infections. Radha 108 will save billions from viral infections & immune disorders

Value of discovery – Unique globally patented Radha108



$150Mn. in addition to govt. funding & sweat equity is $500Mn.

Global Health Challenges – Millions suffer from



Allergy & Asthma



Zika , Ebola, Swine Flu



HIV, TB, RA

Pandemics like Swine flu, Allergies, Asthma, HIV, TB, Ebola, Zika impact global economies & 1 in 3 children miss school due to poor immunity

Source : Lancet & TOI studies

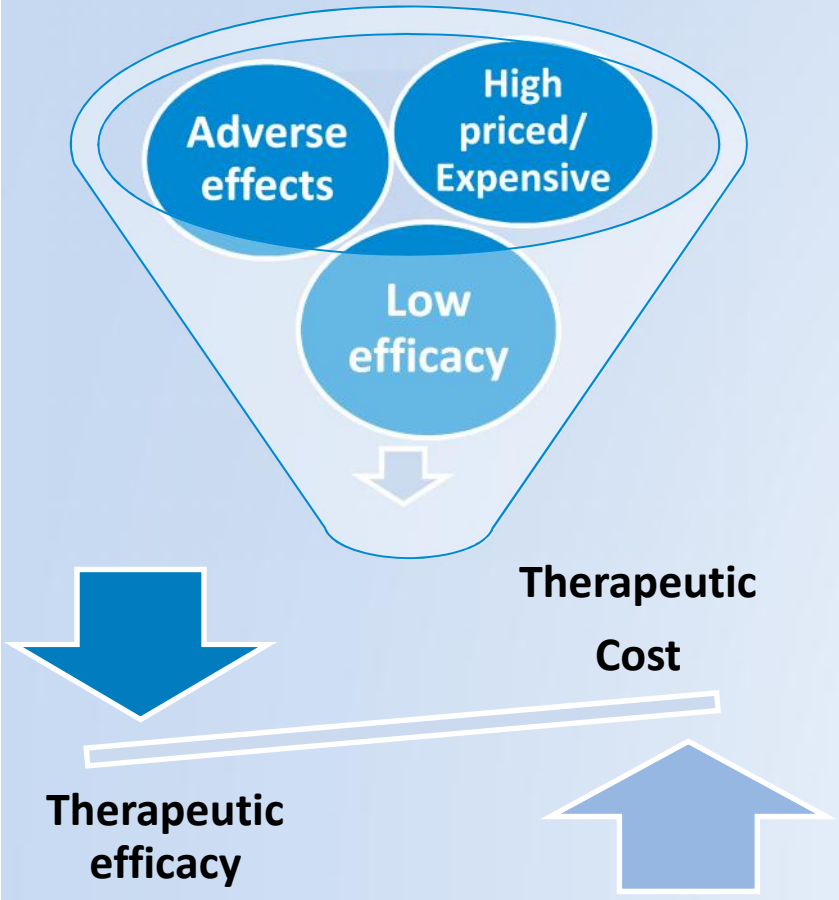
MILLIONS MORE



SWINE FL… B & C HERPES SIMPLEX I&II ACUTE &
CHRONIC … ONS DENGUE FEVER HUMAN PAPILLOMA
VIRUS … VIRAL DIARRHEA ALLERGIES & ASTHMA
TUBERCU… PLASIA HEPATIC CELLULAR CARCINOMA
HYPERTE… AL THRUSH AUTISM PREMENSTRUAL
SYNDROM… ARTHRITIS SPINAL MUSCULAR ATROPHY

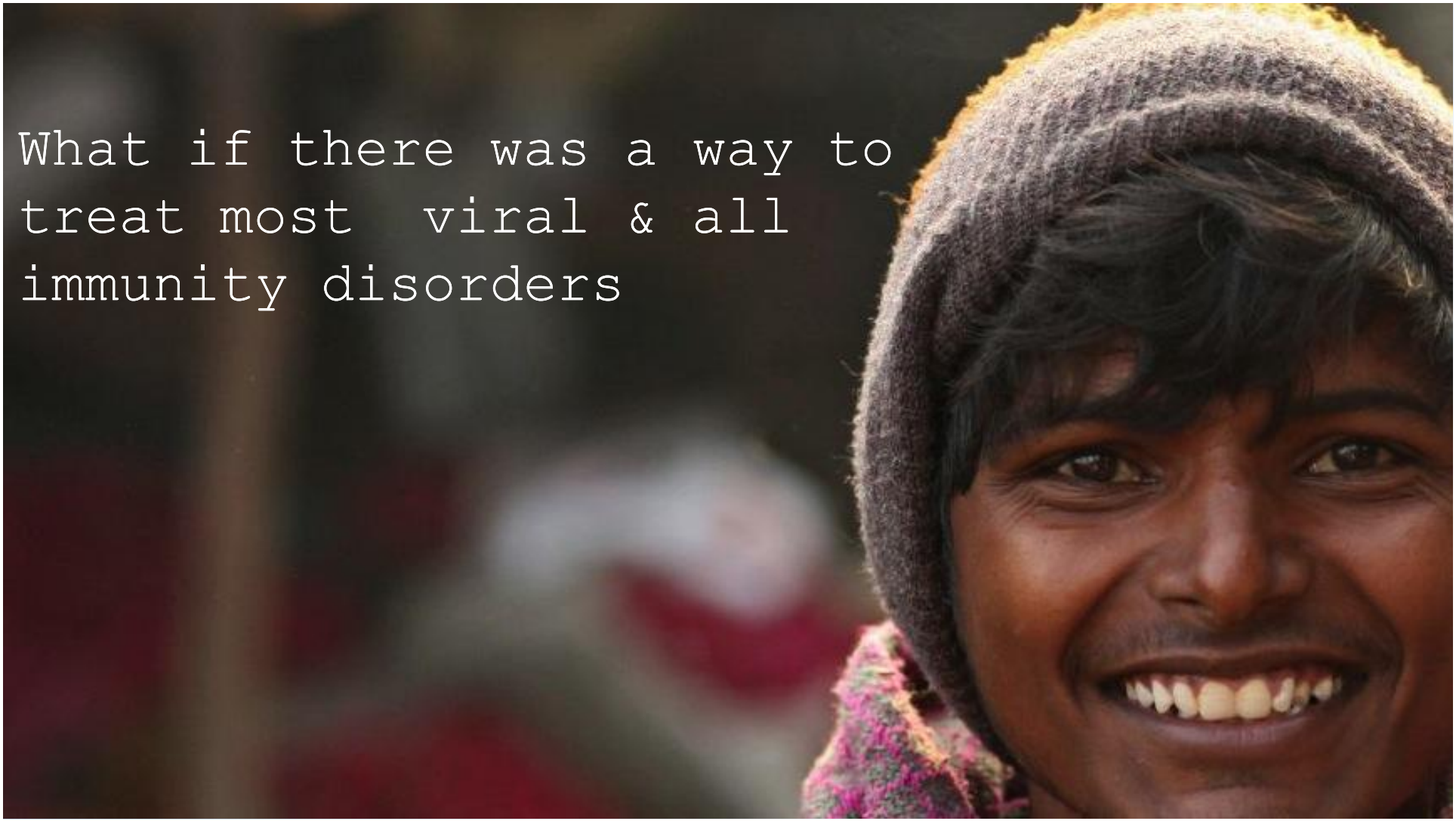
SUFFER FROM
IMMUNE SYSTEM
RELATED ILLNESSES

Challenges with biosimilar



Current Therapeutic cost modalities

Sr. No	Cytokine Biosimilar	Brand Name	Cost
1	Interleukin 2	Proleukin (Aldesleukin), Denileukin Diftitox	Each vial price US $1000
2.	Interferon α	Intron A/ Rebetron/ PEG- Intron, Roferon A	Each vial price US $300
	Interferon γ	Actimmune	Each vial price- US $ 200


What if there was a way to
treat most viral & all
immunity disorders

Uniqueness of NID

Innovative &
Affordable Patented

Broadspectrum Drug
Easy To Administer

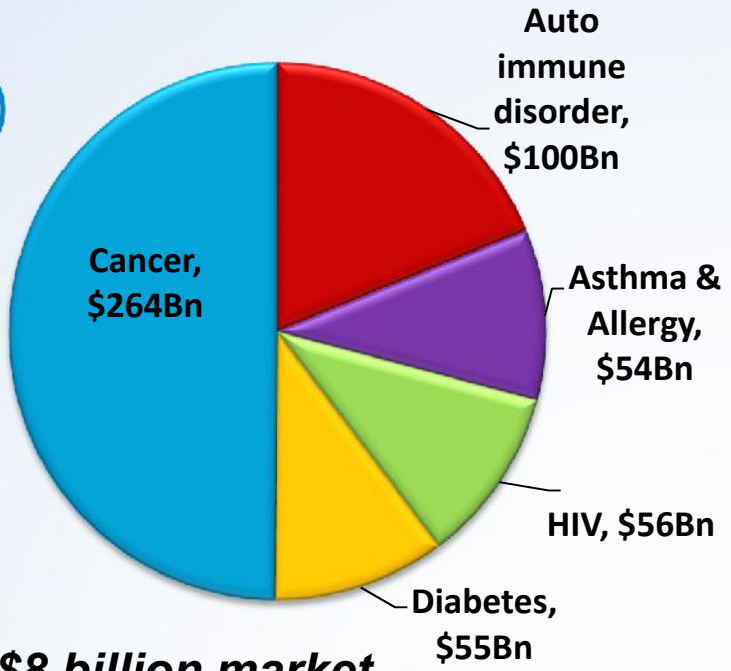
Anti Viral/Immuno-Modulator
with no side effects

Can be consumed by all.. has no age or sex barrier, drug , drug interaction

1 out of 3 Americans can be treated with Radha 108 : $10+ billion drug globally

* Unit sale 250Million for Auto Immune, Asthma, Allergy & HIV Patients in US alone

*US alone accounts for **$5 Billion**

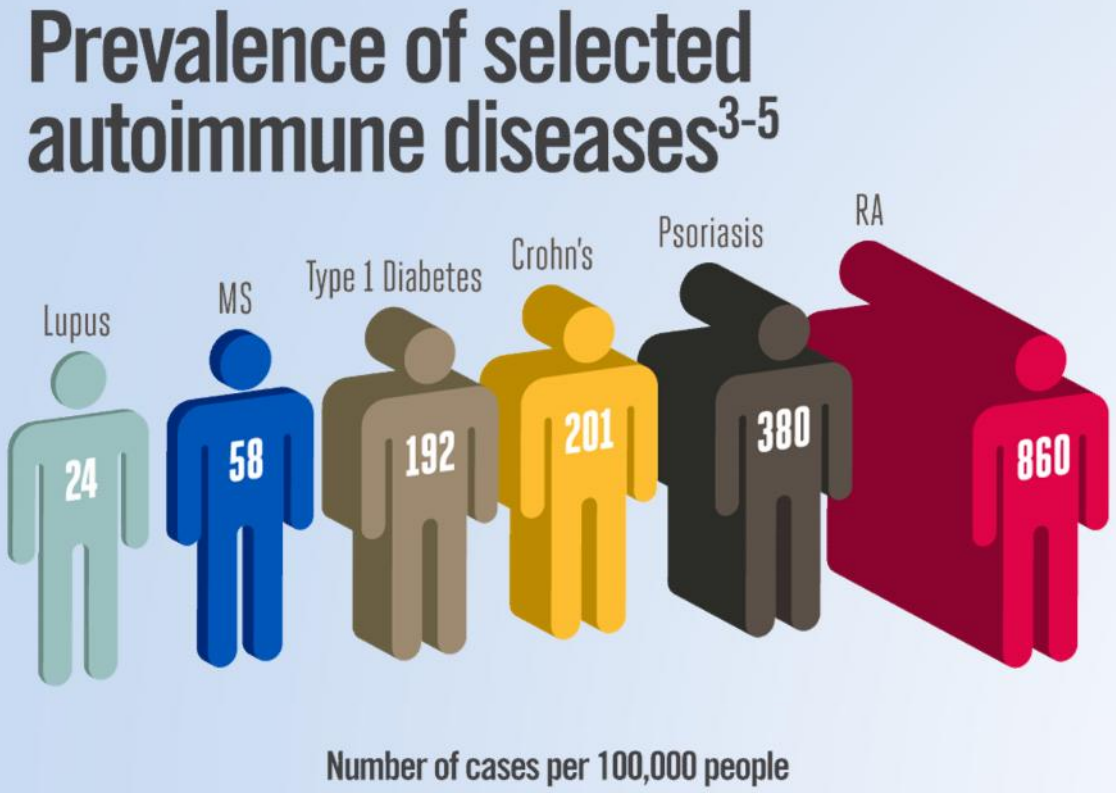


Rest of the world can account for additional $8 billion market

** Radha 108 dosage of 4 times/day @ 3ml/ dose - 3 bottles/month/patient @$40 = $1440 / patient per year*

Source: www.cdc.gov

Auto immune disorders



In US alone, more than 23M people are affected by autoimmune diseases!

More than $100Billion is spent by sufferers on drugs every year!

Asthma

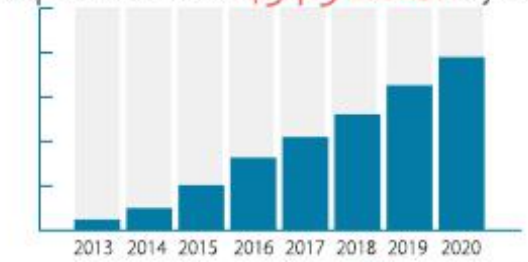
25MM alone in US

Asthma may affect as many as 334 million people.*

EXPECTED TO GROW BY MORE THAN 100MM BY 2025!

Global COPD and Asthma Devices Market

Global COPD and Asthma DevicesMarket is Expected to reach $34.3 Billion by 2020



Growing at a CAGR of 4.5 % (2014-2020)

Global COPD and Asthma Devices Market By Product Type

- Inhalers
  - Drug powder inhalers (DPIs)
  - Metered Dose Inhalers (MDIs)
  - Soft Mist Inhalers (SMIs)
- Nebulizers
  - Compressor nebulizer
  - Ultrasonic nebulizer
  - Mesh nebulizer

Global COPD and Asthma Devices Market By Geography

Asia-Pacific, North America,LAMEA

Europe

Fastest Growing Segment at a CAGR 4.8% (2014-2020)

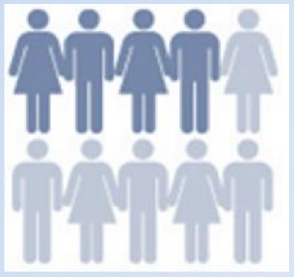


***Source**: www.GlobalaAthmaReport.gov

Allergies & Asthma



Adults



Children

30% adults and **40%** of children worldwide are affected by allergies!

$25Billion is spent on Asthma drugs annually which has gone up by 50% since 2009!

***Source**: www.GlobalaAthmaReport.gov

HIV is a major threat affecting ~40m people worldwide and the sales for HIV drugs are expected to increase steadily

1.2M only in US



36.9 MILLION

people worldwide are currently living with HIV/AIDS.

Source: www.aids.gov

The vast majority of people living with HIV are in low- to middle-income countries, particularly in Sub-Saharan Africa.

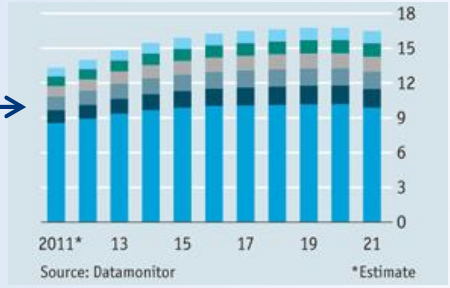


2.6 MILLION CHILDREN

worldwide are living with HIV. Most of these children were infected by their HIV-positive mothers during pregnancy, childbirth or breastfeeding.

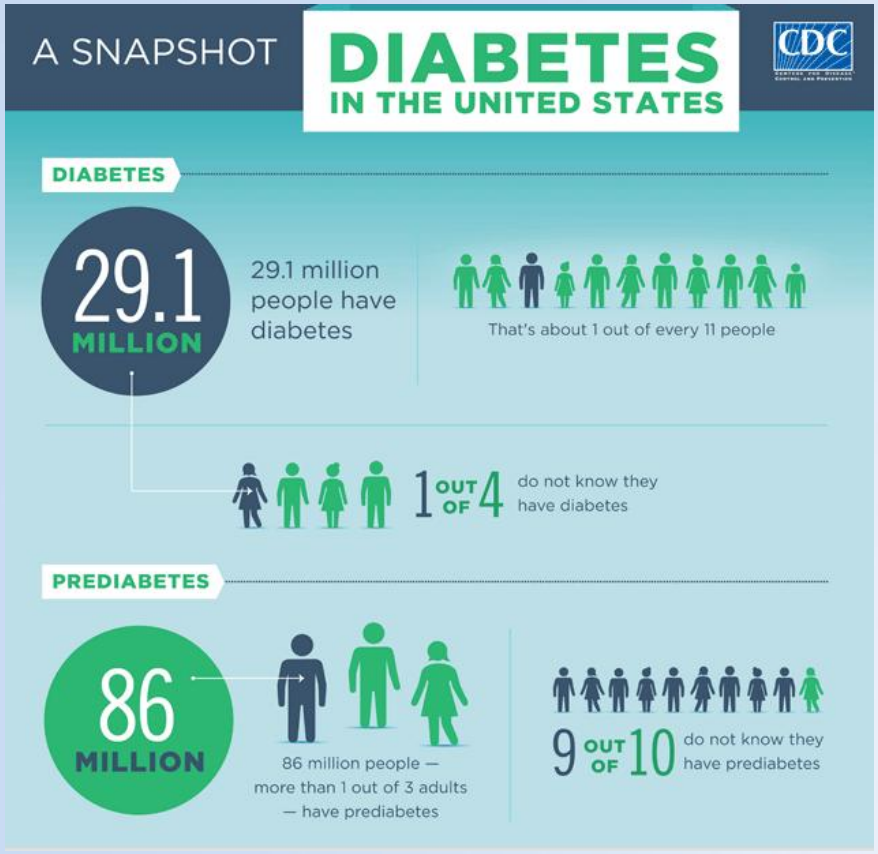


Forecast of HIV drug sales ($Billion)





Diabetes



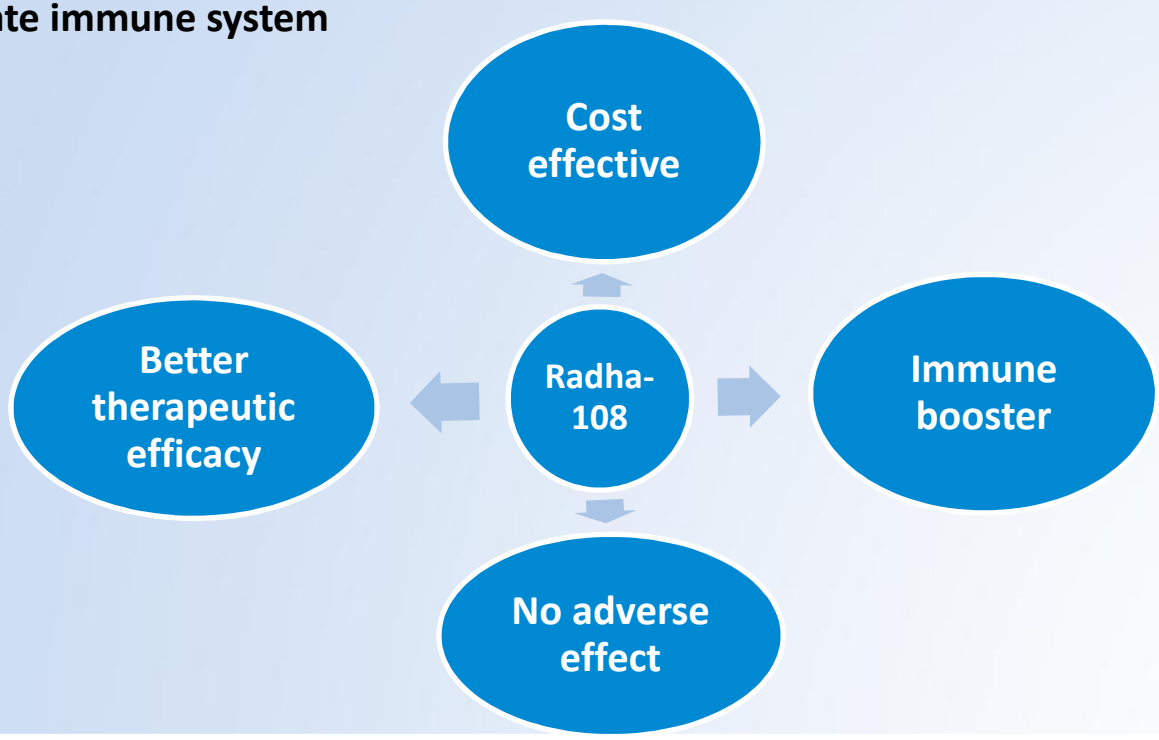
246M worldwide are affected by Diabetes!

$55Billion is spent on annually which has gone up by 55% since 2012!

***Source**: www.cdc.gov

Health for all via New Immunity drug*

Derived from Colostrum : Naturally producing Biosimilar like Cytokines & Chemokines from Cytotoxic T-cells of the innate immune system



* Radha 108 & Secretion of Biosimilar(IL, IF & TNF) via its MoA

What is NID (Radha 108 & its Biosimilar)

Radha 108 Active Pharmaceutical Ingredients (API)

- **API consist of Patented Nano – Informational Peptides extracted from mammalian colostrum via Ultra Nano filtration Technology having sequence id 1-8** ***(provided on next slide)*** **& Proline Rich Poly Peptides (PRPs)**

- **PRPs & Radha-108 are a class of nano informational peptide consisting of oligo-ribonucleotide attached to a peptide molecule that act as immunity drug via immune-modulation and anti-viral/bacterial activity.**

- **Dosage - 3ml QDS via oral buccal spray (1 ml contains 0.03 grams of Patented Nano Peptides that can be synthetically manufactured also) and tablets, capsules & MMS drug delivery systems**

The 'Biggest' thing in Industry, just may be the 'Smallest' thing – Radha 108 Nanopeptides

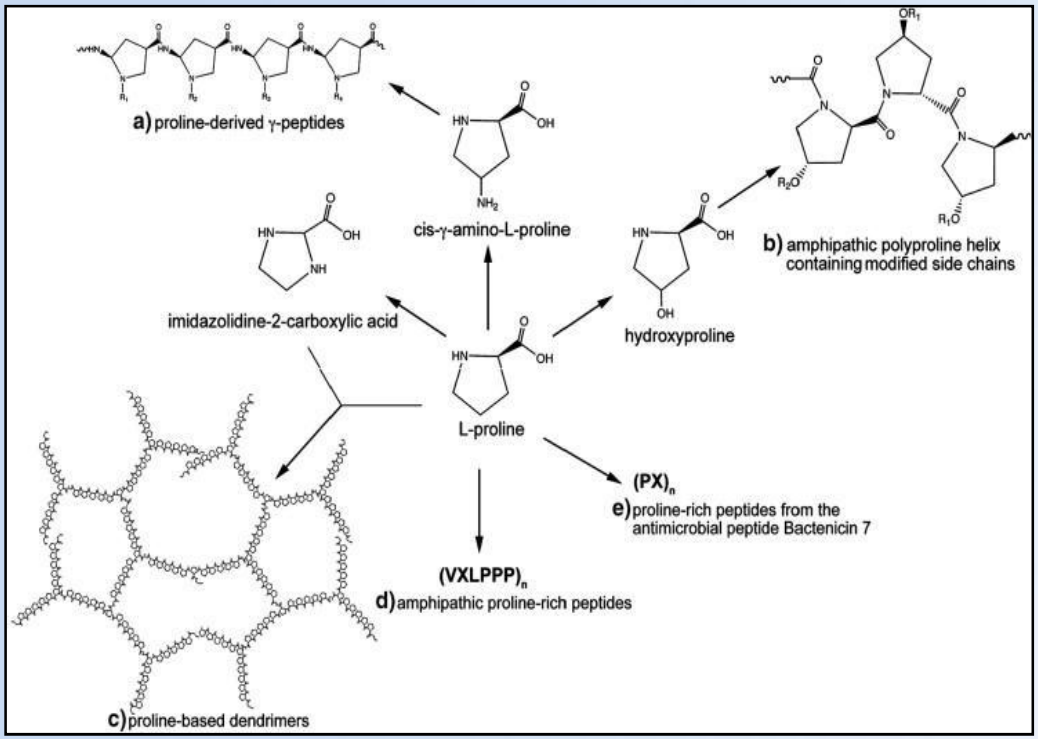
Patented Sequences of NID

Radha 108 containing Patented SEQID-8 that work in synergy with each other to build body's strong immune system even in totally immuno-compromised AIDS patients

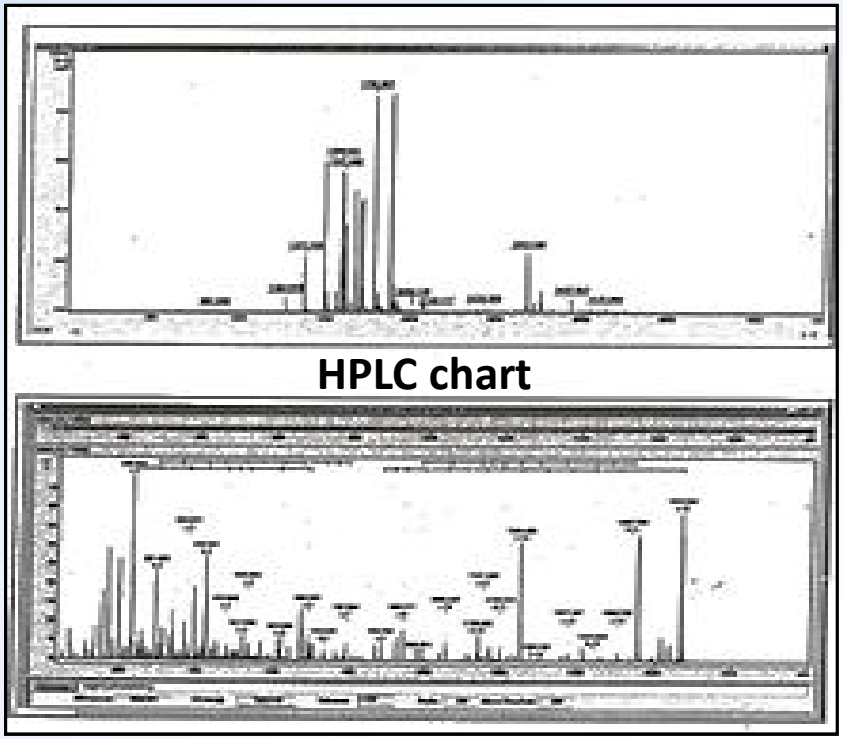
S. No.	Peptide Sequence	Spectral Count	Protein name
1	ELVPGVPRGTQL	27	DNA-binding protein inhibitor ID-3 **(MW – 1265.48)**
2	VAIIQHMIKKLR	24	Epstein-Barr virus induced gene 2 (Lymphocyte-specific G protein-coupled rec **(MW – 1449.86)**
3	LPQEVLNENLLRF	22	Alpha-S1-casein **(MW – 1584.84)**
4	RLNARMAELR	21	S-adenosylmethionine synthetase isoform type-1 **(MW – 1229.47)**
5	SSLQVLNMSHN	21	Toll-like receptor 4 **(MW – 1229.37)**
6	EYQELMNVK	20	Keratin, type II cytoskeletal 59 kDa, component IV (Fragment) **(MW – 1153.32)**
7	VDTLNDEINFLR	20	Keratin, type II cytoskeletal 7 **(MW – 1448.6)**
8	DGIVNENLAER	20	Ribonucleoside-diphosphate reductase small chain **(MW – 1229.31)**

Chemical structure of NID

Proline Rich – Radha 108 (Class V PRP)



Chemical Structure



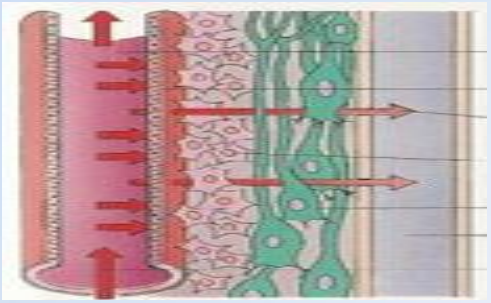
HPLC chart

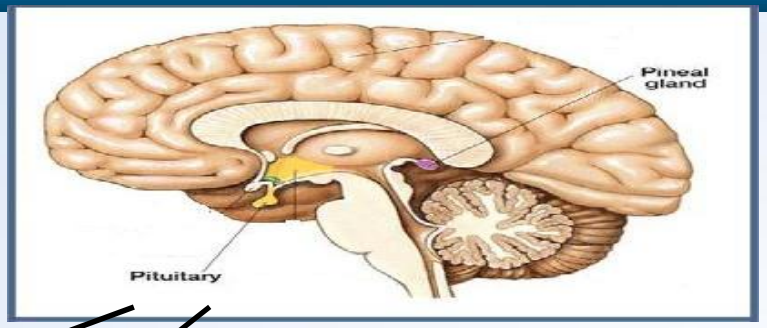
Mass Spectrum

Mode of action: Science behind NID
(Radha 108 efficacy)

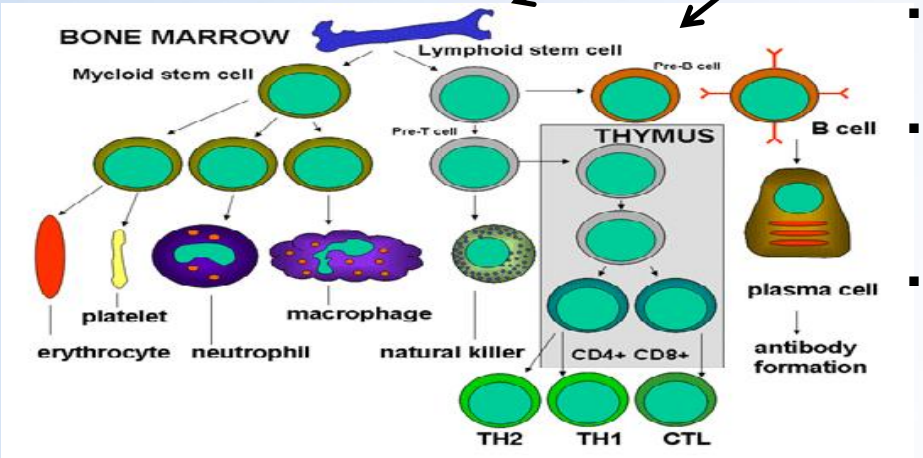


PRPs get absorbed in the blood through buccal mucosa and crosses BBB





- Radha108 (PRP) promotes differentiation of B cells, differentiation and maturation of macrophages and monocytes.
- Activates natural killer (NK) cells, cytotoxic cells of the innate immune system
- Mitigates cell fusion and docks on HIV glycoprotein like Gp120, 180, 160 and 41 mimicking receptor on the cell surface closing entry of viruses.



- Stimulates production of cytokines IL-1 to IL-11, TNF-α, INF–γ.
- Stimulates the maturation of immature thymocytes into either helper or suppressor T cells
- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces

Mode of Action - Pharmacodynamics

- Radha108 series get absorbed in the blood through buccal mucosa and crosses BBB .
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- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces

Mode of action - Pharmacokinetics

Pharmacokinetics

- Radha 108 present in the formulation are readily absorbed through the buccal mucosa into the blood stream to directly reach the immune system. As the molecular weight of the molecules is below 2kdal it can cross any biological barrier including the blood brain barrier. They are readily metabolized and excreted.

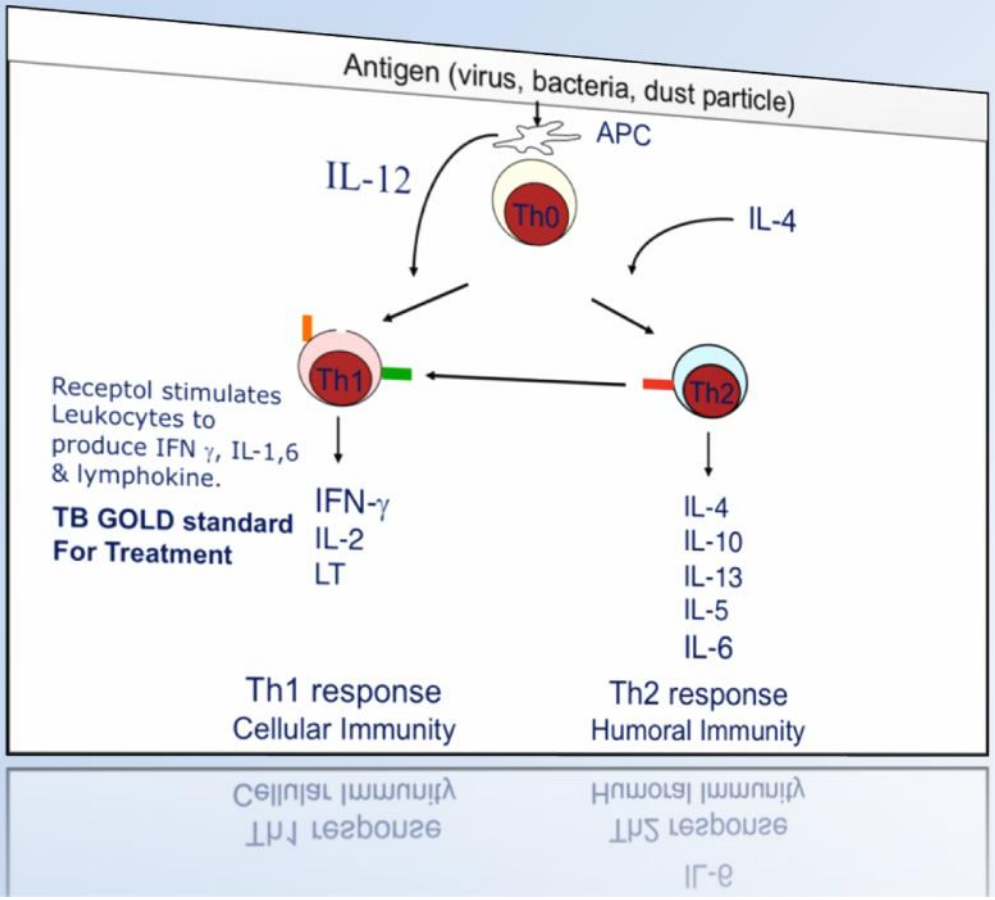
Indications

- The Radha 108 is indicated for all immunity disorders including HIV and recurrent infections as approved by US PTO for 58 indications given in the book on www.biomix.in

Contraindications

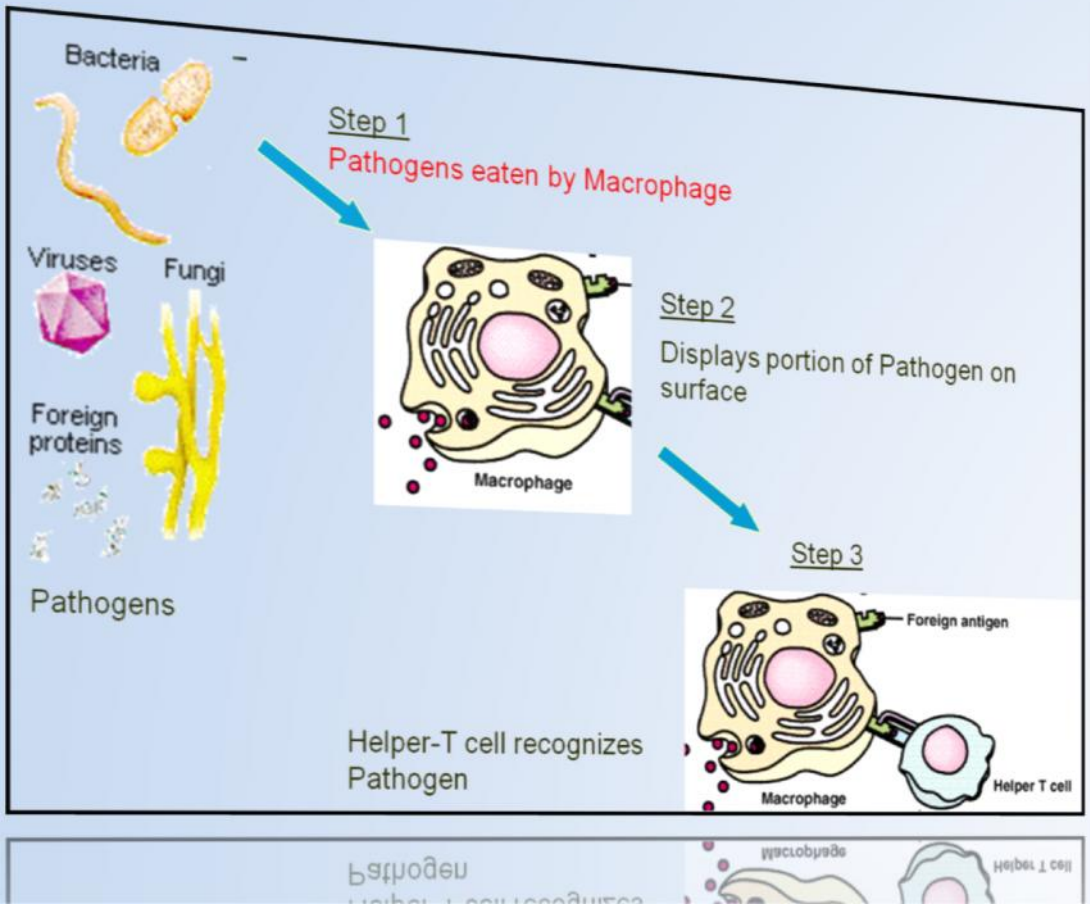
- No adverse effect reported globally for the past 10 years, during global, clinical and operational studies including Acute & Sub- Acute Toxicology Animal study conducted by Indian council of medical research at National institute of nutrition, Hyderabad

Mode of action – T Helper Cell Differenciation



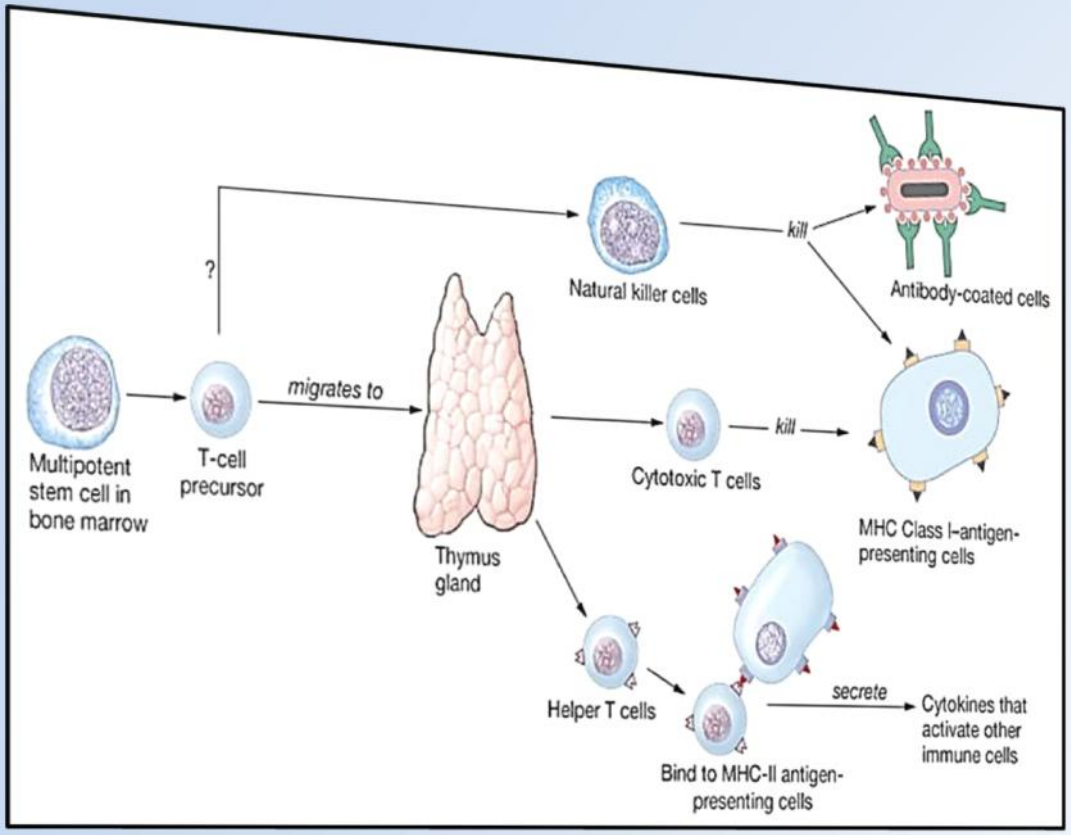
Mode of Action T Helper Cell Differentiation via Radha108 Nanopetides leads to secretion of IFN, IL, TNF and other cytokyres

Mode of action - ↑NK Cells/Microphages



Radha108 Nano Peptide plays role in differentiation and maturation of macrophages and monocytes

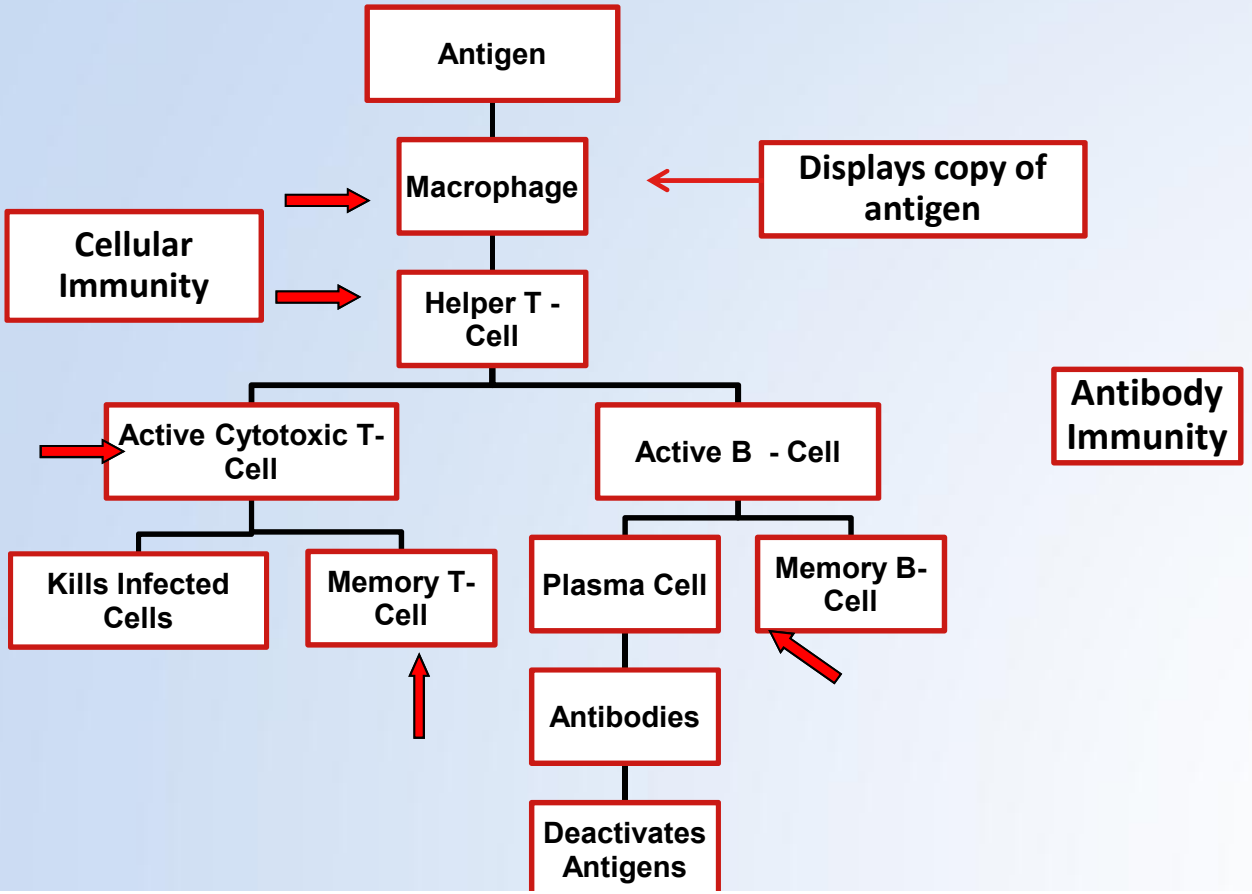
Mode of action - ↑NK Cells



The activity of Natural Killer cells, cytotoxic cells of the innate immune system, was increased up to 5 times by Nanopeptides of Radha108 Nano Peptide

Mode of action - ↑ Immuno Response Summary

Radha 108 (⟶)



GMP Facility & Product Range

- **Radha108 Nano Peptide manufacturing plant is state of the art, nano biotech facility granted by TUV Nord Germany since 2012. GSK Consumer healthcare group UK & India due diligence done on product & the manufacturing facility**

- **Consistent raw material source : International quality from ISO/GMP certified, Amul, world's largest 75 year old dairy with stringent QC/QA checks & balances, right at the origin of Colostrum.**

- **Extraction of API, PRP (Radha108, Type of PRPs of molecular weight from 1800 to 500kDA) is done by Merck Millipore Molecular Exclusion Ultra filtration columns of 100 to 10 kDA at cGMP facility shown below.**





NID – Product range



Oral spray



Oral liquid





Capsules & Tablets



Powder

Medical confirmation of NID for globally patented 58 indications

(US Patent # 9,249,188 PCC# IN2009/000749, WO2010/079511)

Allergies , Asthma, HIV, Autoimmune Disorders,
Viral Respiratory Infection, Rheumatoid Arthritis,
Endometriosis , Cancer, Lupus , Severe Acute
Respiratory Syndrome (SARS), Cold & Flu
Benign Prostatic Hyperplasia ,
Premenstrual syndrome,
& Alzheimer's, Hypertension,
Thrush,Austism, Perthes disease,, Prion disease,
Psoriasis,
Sjogren's syndrome, Spinal Muscular Atrophy,
Thrombocytopenia, Burns, Infection, Insect bites,
Daiper rash, Herpetic lesions, Pharangitis, Porphyria,
Raynaud's phenomenon, Acute Viral Infection,
Dengue fever, Shingles,
, Plantar Warts,
Lymphoma , Herpes Simplex I & II, Parvo,

Sarcoidosis, Celiac disease, Chronic Pancytopenia,
Crohn's disease, Diabetes type II,
Fibromyalgia Rheumatica, Mononucleosis,
Multiple Sclerosis,,
Osteo Arthritis, Brown Recluse Spider Bite,
Corneal Regeneration, Diarrhea,
Guillain Barre Syndrome, Hemolytic Anemia,
Idiopathic thrombocytopenia purpura,
Myasthenia Gravis, Tuberculosis,
Human Immunodeficiency Virus(HIV),
Hepatitis A and C, Rabies in Dogs,
Human Pappilloma Virus

Entry barrier via Global product patents

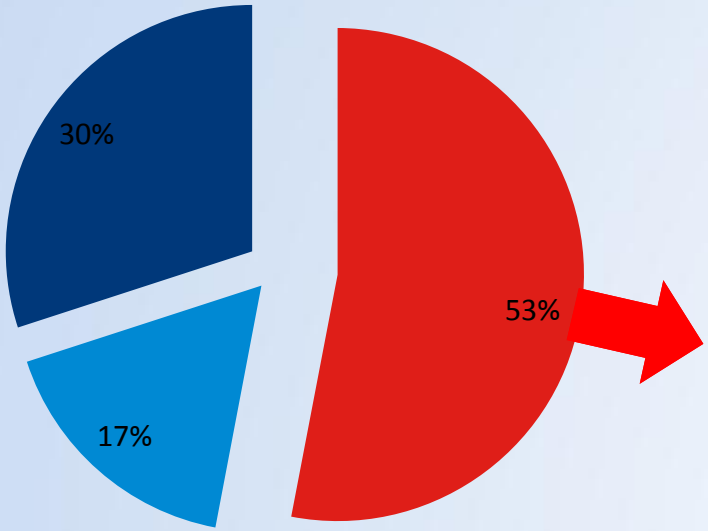
Jurisdiction	Application No./ Date	Title	Status
USA	13/142,327 DT. 27.06.2011	Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED (PATENT# US8518454)
USA	U.S. Patent Application No. 13/845,577	Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof **(For approved 58 indications for Radha 108)**	GRANTED (Patent No. 9,249,188)
SOUTH AFRICA	2011/4687 DT. 24.06.2011	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED (PATENT # 2011/04687)
SINGAPORE	201104717.2 DT. 29.12.2009	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED (PATENT # 172793)
INDIA	1353/MUM/08 DT. 27/06/2008	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
EUROPE	EP 09827010.1 DT. 30.06.2011	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
CANADA	2478449 DT. 29.12.2009	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
PCT	PCT/IN09/749 DT. 29.12.2009	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
Hospital on chip	PCT/IN2011/000522 09.08.2011	An Automated Integrated System, Method and Plate form For Healthcare Services	Granted(PATENT #:WO2012/020429)
Lab on chip	PCT/IN2010/000424 DT. 18.06.2010	An Apparatus and Method For Detecting Biological State in Sample by Using Bio Marker ERS	Granted (PARENT #:WO2011/158246A1)

Business Opportunity through breakthrough innovation

- **Radha108(NID) enables people to lead longer & healthier lives via building body's own immune system naturally and saves billions from viral infections & Immune disorders.**
- **USP of Radha108 is its clinically proven Mode of Action via global study.**
- **Granted product patent in North America, Europe and Asia PAC.**
- **Innovation led Radha 108 NID has potential to be a blockbuster drug($10 Billion+) as illustrated by a series of globally accredited market research conducted by IPSOS & IRMA/IIM indicating Radha 108 as doctors first choice based on its USP, convenience of use & no side effects.**
- **Clinically proven indications of NID include Asthma, Allergy, HIV, Auto Immune disorder, diabetes, cancer & other viral respiratory infections, cancer etc (that accounts for expenditure of $500 billion in US alone. Source- www.cdc.gov).**
- **Wonder drug of the 21st Century - Creating a Paradigm shift in healthcare/pharma industry from Prevention to Cure.**

Global Clinical Trial
Radha 108 in Allergies

Reporting Patients*	:	24
Duration of Treatment	:	6 months

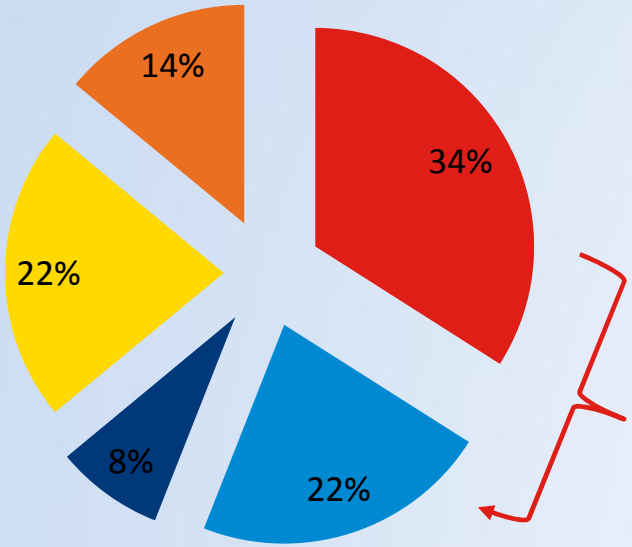


More than half the respondents experienced complete resolution of symptoms!

Global Clinical Trial
Radha 108 in Rheumetoid Arthritis

Reporting Patients* : 63

Duration of Treatment : 6 months



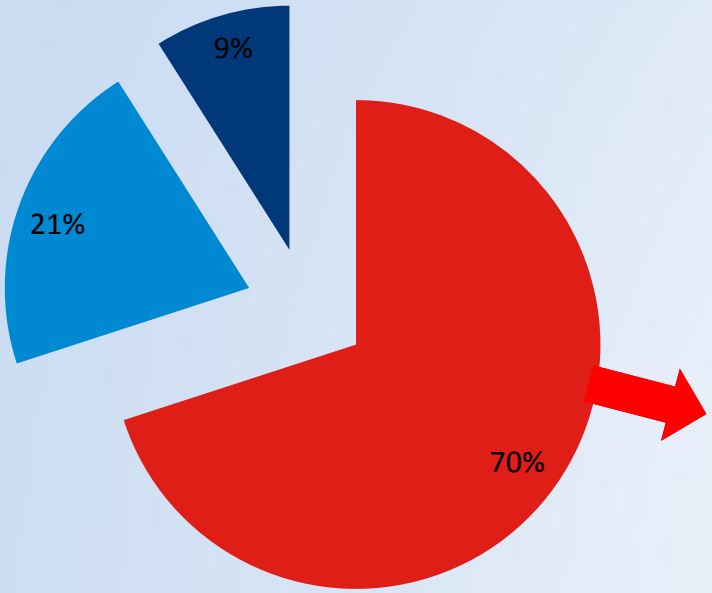
- Complete resolution of symptoms
- Significant benefits
- Some benefit
- Did not exhibit the same benefit
- Inconclusive

56% of patients found the product to be highly effective!

Global Clinical Trial
Radha 108 in Chronic Fatgue

Reporting Patients* : 108

Duration of Treatment : 6 months

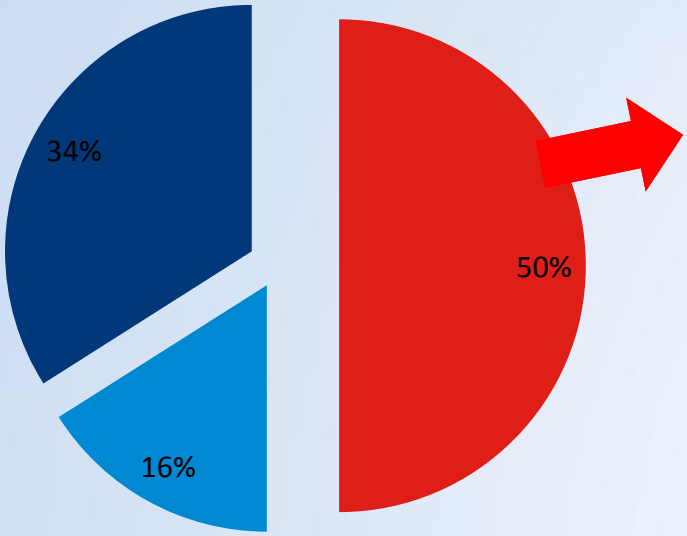


- Significant benefit
- Some Benefit
- Did not exibit the same benefit

70% of patients received significant benefits!

Global Clinical Trial
Radha 108 in Endometriosis

Reporting Patients*	:	106
Duration of Treatment	:	6 months



Similarly for Endometriosis,

complete resolution in most cases!

- Complete resolution of symptoms
- Some benefit
- Inconclusive

Indian Safety & Efficacy Trial

On Immuno compromised HIV subjects used as the model

Preclinical Safety: as per **NIN** National Toxicology Panel

- **No Acute Toxicity & No Sub Chronic Toxicity**

Revalidation Phase III Indian Trials – Stand alone MONOTHERAPY with Radha 108 Nano Peptide sponsored by Government of India, MOH/NACO and Monitored by ICMR/NARI*

- **Study I (2006-07)** : By GoI on 50 Patients at LTMG Hospital Sion, Mumbai (Clinical trial registry No. : CTRI-2012-08-002931)
- **Study II (2007-08)** : By GoI on 51 Patients at LTMG Hospital, Sion, Mumbai (Clinical Trial registry No. : CTRI-2012-09-002959)

The study was fully controlled, conducted and sponsored , by Govt. of India, Biomix was facilitating the same & had no control on the specifications.

Safety and Efficacy Achieved by Global Trials:

Phase I : 12 cohort 30 days (completely safe) in Ohio, USA

Phase II : 30 cohort 90 days (highly effective with no side effects)in Nairobi – Kenya

Phase III : 60 cohort for 365 days (highly effective with no side effects) in Rwanda, Africa

Toxicology study at National institute of nutrition (NIN)

Pre-Clinical safety study has been undertaken as per schedule Y of DCGI guideline under the supervision of Dr. B. Dinesh Kumar, Asst. Director (Study director) at **National Institute of Nutrition, Hyderabad**.

1.	**Animal selected**	**SPRAGUE DAWLEY RATS (of both the sexes)**
2.	**Weight of the animal**	**150–180 gm (for both the studies)**
3.	**Age of the animal**	**4 to 6 weeks (for both the studies)**
4.	**Route of Administration**	**Oral**

Acute toxicity

RESULTS
No pre-terminal deaths after administration of 50 times of intended therapeutic dose through oral route
All rats were found to be active and with normal body weight.
No Acute toxicity found.

**** Indian council of medical research (ICMR)***

NIN Study : Sub acute data

No mortality was observed & product is safe

1.	No. of Rats used	48
2.	Categories	Vehicle control (VC), Therapeutic dose (TD – 1.08ml), Average dose (AD – 5XTD), (five times of TD) and High Dose (HD – 10XTD), (ten times of TD)
3.	Days of trial	45
4.	Period of Observation	Biweekly for live phase, cage side, physical and neurological parameters. At 48hrs and 15th day hematology and biochemistry profile along with gross necropsy and histopathology of major organs were evaluated.

RESULTS
No significant difference in physical activity and neurological activity between control and test groups throughout the study period.
No significant abnormalities in hematology , clinical chemistry profile in blood/serum samples.
No gross lesions were found in any organ and no significant difference in histopathology of various organs.
No sub chronic toxicity found

Global Trial Results
Phase I – Ohio State University, USA

- 12 cohort, 30 days, moderate dose
- Patients may have previous exposure to AZT
- Balanced diet with vitamin-minerals provided
- 10 patients had weight gain and 7 patients had gained an average 6 lbs
- Highest weight gain was 12 lbs for a patient who was HIV positive for 10 years
- All 12 pt had improved symptom assessment score and average reduction approached 63 %

Free of side effects

Phase II – Nigeria, Africa

- Advanced HIV / AIDS, Limited access to conventional treatment
- 30 cohorts, 30 days Mono therapy
- No previous exposure to ART
- Some signs of detoxification, relieved by increase water intake
- Resolution or reduction in all Clinical symptoms
- Weight gain observed in all patients

Efficacious & Free of side effects

Phase III – Rawanda, Africa

- Safety and efficacy trial
- 60 AIDS patients – 365 days
- Patients were unaware of positive potential of drug
- Weight gain consistently observed
- After day 1 moderate level of relief of diarrhea and fever
- After 14 days, relief from skin lesion, mouth thrush, fever, diarrhea, tuberculosis symptoms
- After 90 days relief of all symptoms with increase in Absolute CD4 Counts & Reduction in Viral Load

No adverse effects observed over 12 months follow up with improved Quality of Life even after 5 years of therapy.

Highly Efficacious & Free of side effects

India mono-therapy snapshot

Stand alone Mono-therapy Safety and Efficacy in HIV+ AIDS Patients:

- **Study I – Sion Hospital, Mumbai on 50 HIV+ Patients**
  - Absolute CD4 cell count & HIV Viral Load – tested at NABL accredited Metropolis lab, Mumbai
  - Clinical & Physical symptoms study - at ART Center, OPD Center, Sion Hospital, Mumbai
  - **Inclusion criteria** – absolute CD4 cell count greater than 100 cells/mm^3
  - **Exclusion criteria** – no pre- exposure to ART
  - Mean HIV log viral load has statistically significantly dropped ($p < 0.001$)
  - Statistically significant increase in CD4 cell count ($p = 0.06$)
  - Clinical symptoms disappeared in 3 weeks of treatment in All Patients ($p<0.05$)
  - Statistically significant weekly weight gain in All Patients ($p<0.001$).

Summary of study 1 data (Mumbai, India phase III)

Visit (Weeks)	No. of Subjects with Nausea	No. of Subjects with Vomiting	No. of Subjects with Fatigue/ Malaise	No. of Subjects with Diarrhea	No. of Subjects with Fever	No. of Subjects with Cough
1	8	7	44	9	12	14
2	3	2	32	5	3	10
3	2	2	26	1	6	6
4	1	1	17	1	1	3
6	0	1	1	0	0	1
8	0	0	1	0	0	2
10	0	0	1	0	0	0
12	0	0	0	0	0	0

Sr. No.	CD4 count N=48	Before	After 12 Weeks	p-value
1.	Median	312.5	363.5	0.06
2.	25th Percentile	275.5	294.2	
3.	75th Percentile	430	435	

Sr. No.	Parameter	Before	After 12 Weeks	p-value
1.	Log of HIV-1, RNA (N=34)	5.11(0.090)	4.103(1.32)	< 0.001
2.	Median	206057	25280	< 0.001
3.	25th Percentile	62884	1665	
4.	75th Percentile	508038	87511	

India mono-therapy snapshot

- **Study II – Sion Hospital, Mumbai on 51 AIDS Patients**
  - Absolute CD4 cell count & HIV Viral Load – tested at IIH (ICMR)
  - Clinical & Physical symptoms study - at ART Center, Sion Hospital
  - **Inclusion criteria** – absolute CD4 cell count greater than 100 $cells/mm^3$ and 100% symptomatic patients at basal.
  - **Exclusion criteria** – no pre- exposure to ART
  - Mean HIV log viral load has statistically significantly dropped ($p < 0.009$)
  - Statistically significant increase in CD4 cell count ($p < 0.042$)
  - Clinical symptoms disappeared in 3 weeks of treatment in All Patients ($p<0.001$)
  - Statistically significant weekly weight gain in All Patients ($p<0.001$).

Summary of study 2 data (Mumbai, India phase III)

Clinical Symptoms	N	At Baseline	Responders At Week-2
Diarrhea	51	51(100%)	12(23.53%)
Nausea	51	51(100%)	3(5.9%)
Vomiting	51	51(100%)	17(33.3%)
Fever	51	51(100%)	13(25.5%)
Cough	51	51(100%)	13(25.5%)
Paraesthesia	51	51(100%)	16(31.4%)
Disturbed Sleep	51	51(100%)	0(0%)
Skin Rash	51	51(100%)	7(13.7%)
Fatigue/Malaise	51	51(100%)	51(100%)
Herpes Zoster	51	51(100%)	18(35.3%)
Hair Changes	51	51(100%)	16(31.4%)
Leukoplakia	51	51(100%)	5(9.8%)
Oral Thrush	51	51(100%)	51(100%)

Parameter	Baseline Mean ± SD	Week 12 Mean ± SD	Difference (Week 12- Baseline) Mean ± SD	P-value
CD4 Counts (cells/ cmm)	317.16 ± 128.67	344.24 ± 165.79	+ 27.08 ± 92.47	0.042
CD8 Counts (cells / cmm)	1037.06 ± 285.02	1139.75 ± 386.76	+102.69 ± 267.44	0.008

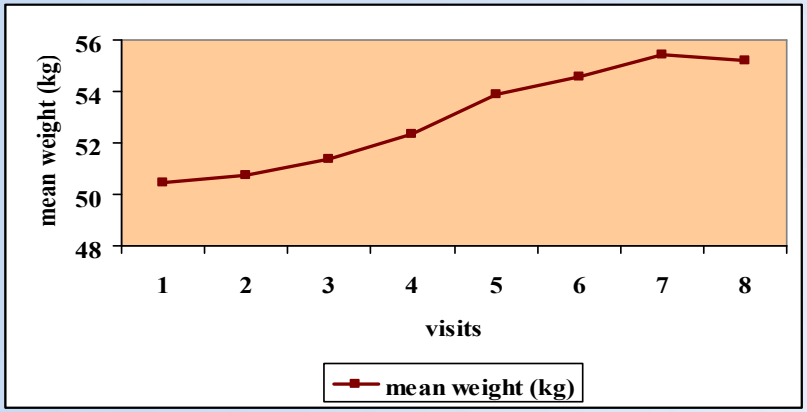
Indian Study : STAND ALONE MONOTHERAPY

SION HOSPITAL MUMBAI

Weight gain after treatment

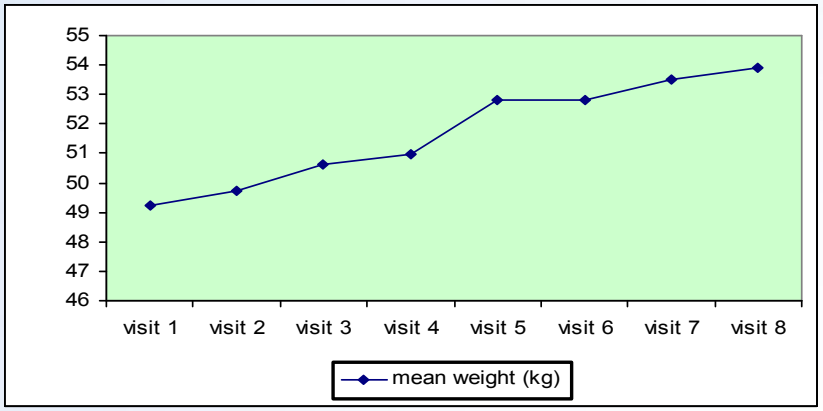
Statistically significant gain in weight p<0.05 in both the Study I and Study II

Study 1



Study I : average weight gain of **4.73 kg** after 12 weeks of Radha 108 therapy. statistically significant ($p < 0.05$)
Mean weight was **50.48 kg** at start of study.

Study 2

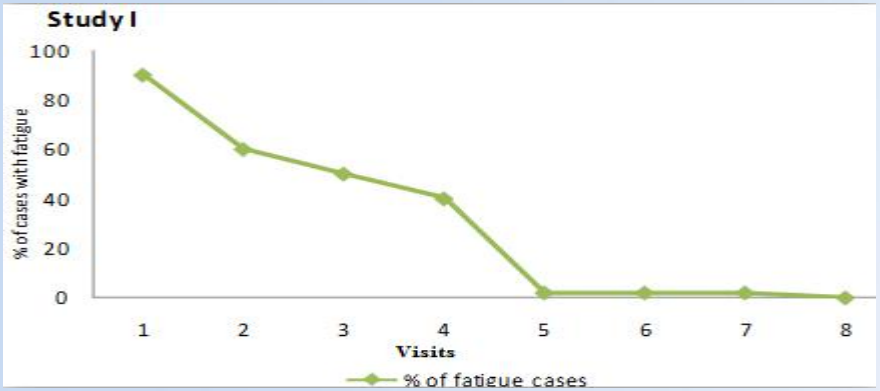


Study II : average weight gain of **4.68 ± 1.9** kg after 12 weeks of Radha108 therapy. statistically significant ($p < 0.05$)
Mean weight was **49.21kg** at start of study and **53.89 kg** after 12 wks.

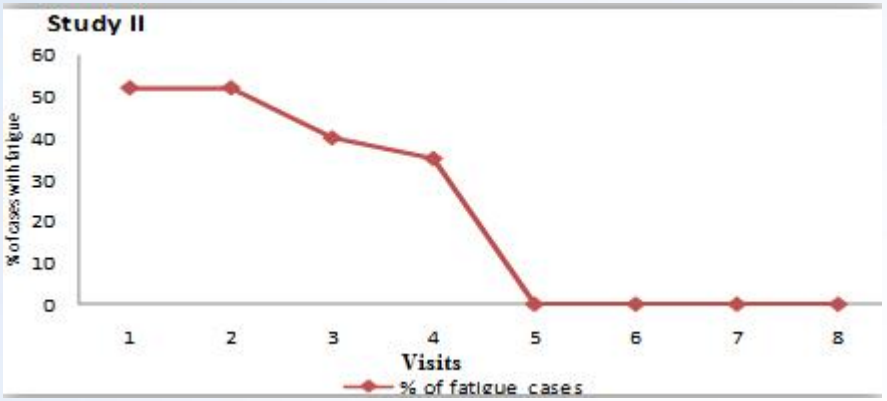
Data on chronic fatigue syndrome after therapy

Statistically significant reduction in Fatigue / Malaise in both the Study I and Study II

Study 1



Study 2



Study I:

- 88 % of the total study cases had fatigue at basal.
- After 6th week onwards only one or two patients had fatigue, statistically significant

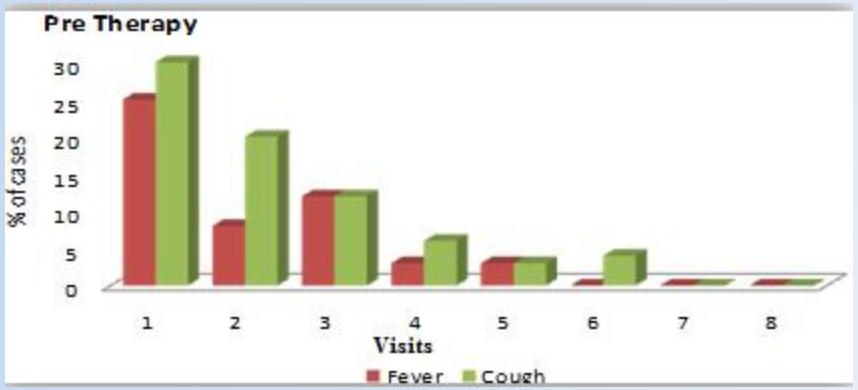
Study II:

- 100 % of the total study cases had a symptom of fatigue at basal. At the end of 2nd week proportion of symptoms of fatigue had a statistically significant fall from basal.

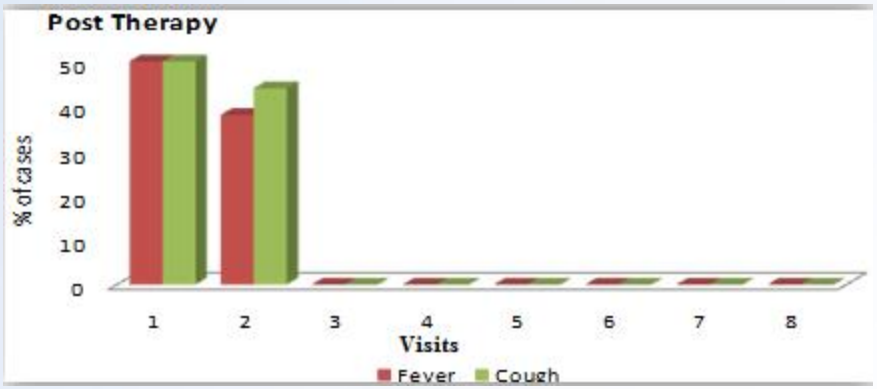
Data on fever & cough after Therapy

Statistically significant reduction in Fever and Cough in both the Study I and Study II

Study 1



Study 2



- Study I: Fever and cough was reported by 24 % and 28% of total study cases at basal respectively. After treatment at the end of 4th week proportion of patients with symptom of fever and cough had a statistically significant fall

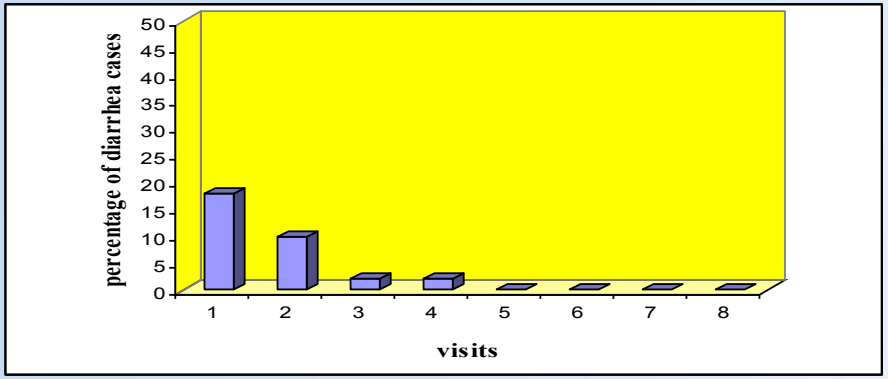
Study II: 100 % of the total study cases had fever and cough.

after treatment from 3rd week onwards all the patients had relief from fever and cough, statistically significant

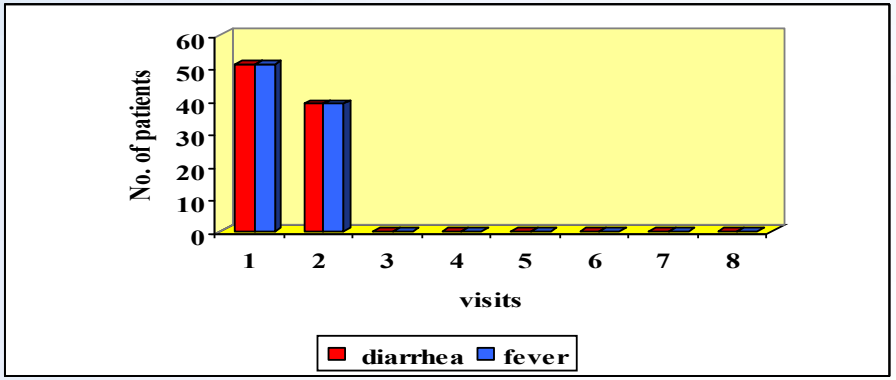
Data on Diarrhea after Therapy

Statistically significant reduction in Diarrhea in both the Study I and Study II

Study 1



Study 2



Study I: 18 % of the total study cases had diarrhea at basal and after treatment from 5th week onwards all the patients had relief from diarrhea, statistically significant

Study II: 100 % of the total study cases had diarrhea at basal and after treatment from 3rd week onwards all the patients had relief from diarrhea, statistically significant

Data on HIV viral load after Therapy

Statistically significant reduction in HIV Viral Load

Study 1

	Viral Load baseline	Viral Load 3 months
Mean	335278.23	141053.42
Median	92457.50	25332.50

Study I: The mean HIV log viral load has statistically significantly dropped from 4.63 to 4.18 after 12 weeks of treatment.
($p = 0.03$)

Metropolis Health Services (I) PVT. LTD. Laboratory, Mumbai (NABL & CAP accredited)

Study 2

	Viral Load baseline	Viral Load 3 months
Mean	119243.49	38814.33
Median	38108.00	14073.00

Study II: The mean HIV log viral load has statistically significantly dropped from 4.41 to 4.02 after 12 weeks of treatment.
($p = 0.009$)

Institute of Immuno Hematology (IIH), an ICMR Institute, KEM Hospital, Mumbai

Data on CD4 Cell Count after therapy

Statistically significant increase in CD4 Cell Count

Study 1

	CD4 baseline	CD4 3 months
Mean	370.63	390.65
Median	312.50	363.50

Study I: There was increase in CD4 count on the average by 51 (median CD4 cell counts from 312 to 363). this is of statistical significance
(p = 0.06)

Study 2

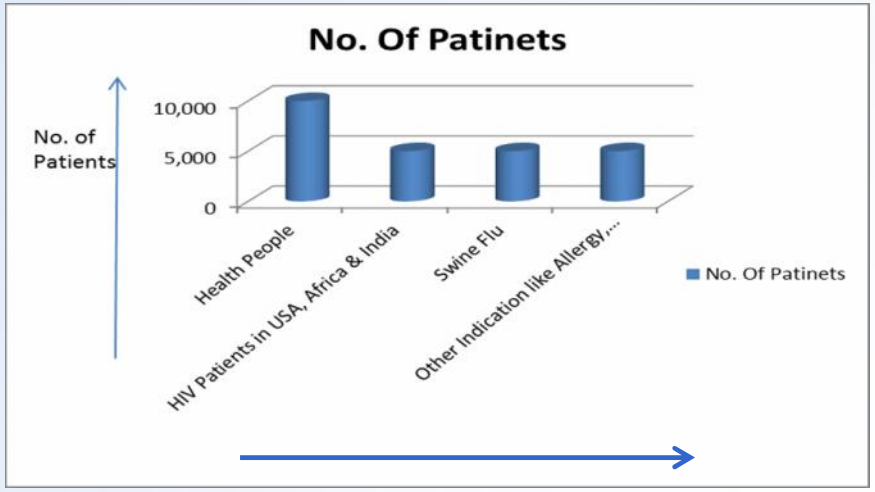
	CD4 baseline	CD4 3 months
Mean	317.16	344.24
Median	276.00	305.00

Study II: There was increase in CD4 count on the average by 27 (median CD4 cell counts from 276 to 305). This is of statistical significance
(p = 0.042)

Meta Analysis on 25000 Patients

- **Meta Analysis is a combined Statistical analysis of 25,000 subjects across HIV, Swine Flu, Allergy/Asthma, Rheumatoid Arthritis , Endometriosis & NCD: Chronic Fatigue Syndrome showing increase in weight gain as an Indication of overall wellness showing Safety & Efficacy of Radha108 Nano Peptide.**

Sr.No.	Stand Alone Receptol Therapy in Global clinical studies	No. of Patients
1	Healthy people	10,000
2	HIV Patient in USA, Africa, India	5000
3	Swine Flu	5000
4	Other Indications like allergy, asthma, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Endometriosis Study etc.	5000



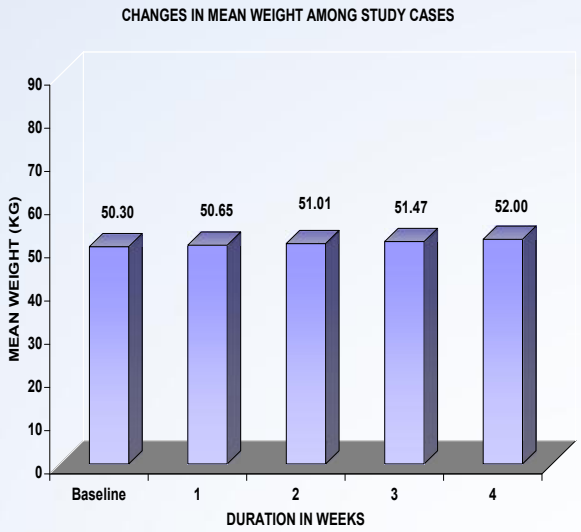
Stand Alone Radha 108 Therapy in Global Clinical Studies

Efficacy & safety of on Healthy Population

CHANGES IN MEAN BODY WEIGHT AMONG STUDY CASES

Duration (Weeks)	Mean weight ($\bar{X} \pm SD$) (N = 10000)
Baseline	50.30 ± 10.02
1	50.65 ± 10.01
2	51.01 ± 09.96
3	51.47 ± 09.94
4	52.00 ± 09.96
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.66 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.71 ± 01.24 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.17 ± 01.95 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.70 ± 02.15 (0.001)

By ANOVA P<0.05, * Significant

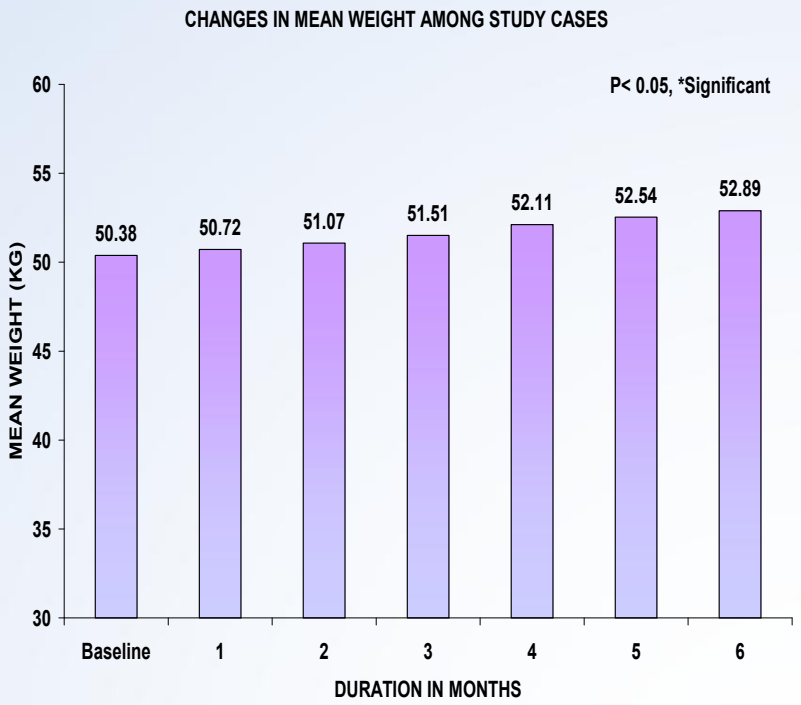


- After 1 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 0.7% from baseline.
- After 2 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 1.4% from baseline. Same trend was observed till the end of 4 weeks

Efficacy & safety of on HIV+ patients in USA, India

CHANGES IN MEAN WEIGHT AMONG STUDY CASES

Duration (Months)	Mean weight ($\bar{X}$ ± SD) (N = 5000)
Baseline	50.38 ± 09.89
1	50.72 ± 09.88
2	51.07 ± 09.82
3	51.51 ± 09.79
4	52.11 ± 09.75
5	52.54 ± 09.76
6	52.89 ± 09.77
Mean Diff. (Baseline – 1 month) (P value)	*00.34 ± 00.57 (0.001)
Mean Diff. (Baseline – 2 months) (P value)	*00.69 ± 00.91 (0.001)
Mean Diff. (Baseline – 3 months) (P value)	*01.13 ± 01.39 (0.001)
Mean Diff. (Baseline – 4 months) (P value)	*01.73 ± 01.71 (0.001)
Mean Diff. (Baseline – 5 months) (P value)	*02.16 ± 01.76 (0.001)
Mean Diff. (Baseline – 6 months) (P value)	*02.51 ± 02.07 (0.001)



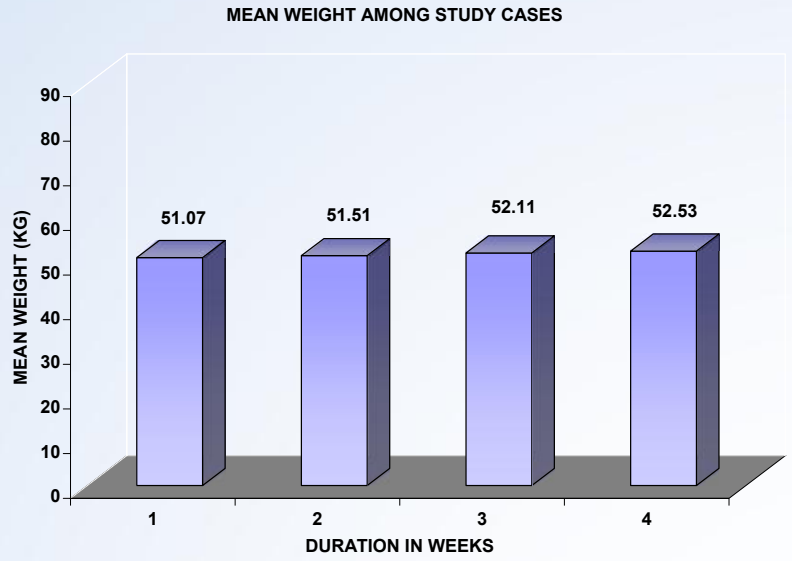
By ANOVA - Significant

- After 1 month of treatment, mean weight showed a significant rise of 0.7% from baseline.
- After 2 months of treatment, mean weight showed a significant rise of 1.4% from baseline, similar trend was observed till the end of 6 Months.

Efficacy & safety of on Swine flu

CHANGES IN MEAN WEIGHT AMONG STUDY CASES

Duration (Weeks)	Mean weight ($\bar{X}$ ± SD) (N = 5000)
1	51.07 ± 9.82
2	*51.51 ± 9.79
3	*52.11 ± 9.75
4	*52.53 ± 9.76

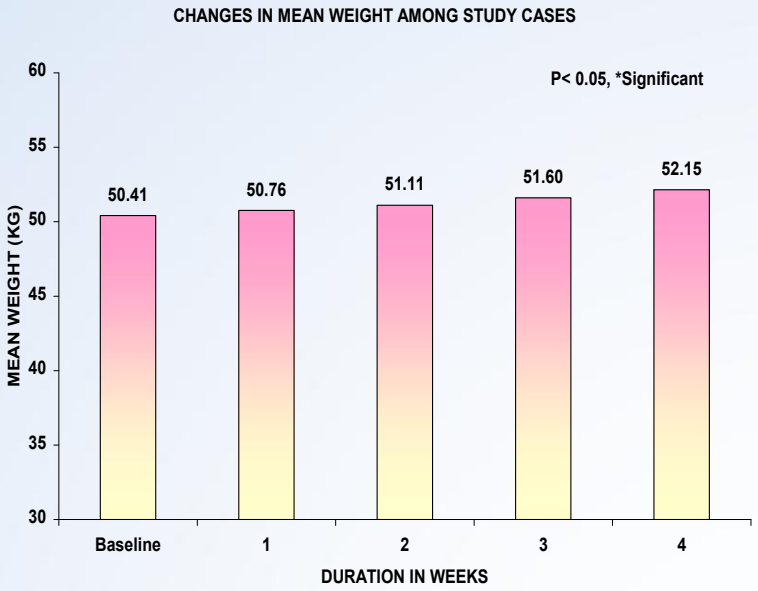


By ANOVA P < 0.05, * Significant

- At the end of 2nd week, mean weight showed significant change from baseline i.e. mean change of 1.44 kg.
- At the end of 4th week mean weight increased significantly that is 1.46 kg from baseline.

Efficacy & safety of other indications like allergy, asthma, arthritis, diarrhea, fever, fatigue-malaise, anemia, endometriosis

Duration (Weeks)	Mean weight ($\bar{X}$ ± SD) (N = 5000)
Baseline	50.41 ± 10.03
1	50.76 ± 10.01
2	51.11 ± 09.94
3	51.60 ± 09.91
4	52.15 ± 09.91
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.57 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.70 ± 01.05 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.19 ± 01.77 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.74 ± 01.95 (0.001)



By ANOVA *** Significant**

- After 1 week of treatment, mean weight showed a significant rise of 0.7% from baseline.
- After 2 week of treatment, mean weight showed a significant rise of 1.4% from baseline, similar trend was observed till the end of 4 weeks.

Conclusion by Dr. Kailash Ghandewar, Biostatistician

- **This observation study reveals that after Radha108 Nano Peptide oral spray therapy provide significant efficacy & safety in all groups of patients with increased QoL with weight increase in chronic patients.**

- **Hence these results indicate that Radha108 Nano Peptide oral spray is very effective and safe among cases with indications like HIV, Swine flu, Allergy, Asthma, Arthritis, Diarrhea, Fever, Fatigue-Malaise, Anemia, Endometriosis etc. showing increase in weight gain as a parameter for overall wellness and improved quality of life, even in healthy population.**

Team

- Founder CEO
  - Dr. Pawan Saharan, MS, PhD (JNU, WVU)
    - AMP (ASCI in tie up with Harvard business school)
    - Best US graduate student award by AAAS with fellowship at Stanford University
    - Email id: biomix108@gmail.com / drpawan@biomix.in
- Research Director
  - Dr. C. R. Bhatia, Ph.D., Post Doc. (BNL, NY, US),
    - DBT Secretary Govt. of India & Director: BARC, Advisor: IAEC, Vienna
    - Email id: bhatia@gmail.com
- Project Director
  - Amitabh Thakore, B. Tech., MBA (IIM- Ahmadabad)
    - Email id: agthakore@yahoo.com

- Medical Directors
  - Dr. S.H. Advani, MD, FICP, FNAMS
  - Oncologist & President - Asian Cancer Society
  - Padamvibhusan awardee by President of India
  - Email id: shadvani2000@yahoo.com
- Dr. Sushil Indoria , MD
  Medical Director Life care Hospital, Thane
  Email id: Sushilindoria@yahoo.in
- Dr. Sandhya Saharan, MD, DGO, Gynecologist and IVF specialist. Email id: drsandhyasaharan@hotmail.com
- Dr. Ali Irani - President API, Ortho & Sports Medicine
  Former Physiotherapist of Indian Cricket Team (12 years)
  Email Id: dralirani@gmail.com

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