

# atlantia

food clinical trials



A global leader in performing clinical studies, to **ICH-GCP** standards



A unique business model, we operate our **OWN CLINICS**

# Tour of facilities - Cork



13 clinic rooms

Central phlebotomy lab



Locked -80° storage

Locked refrigerated/ambient storage

Sample preparation Lab



Board room

Meeting rooms

# Tour of facilities - Chicago



15 clinic rooms

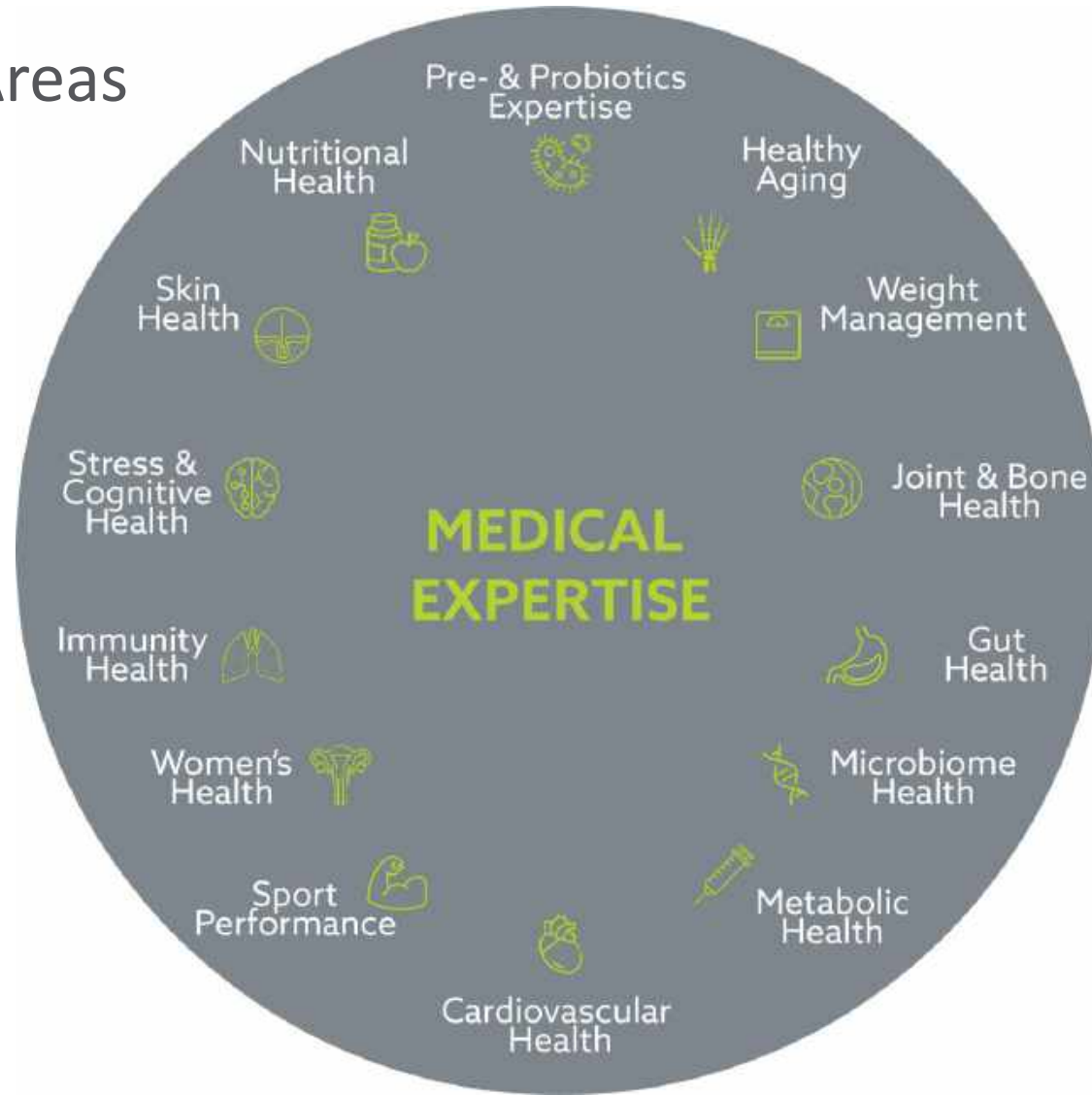
Central phlebotomy lab

Locked -80° storage

Locked refrigerated/ambient storage

Sample preparation Lab

# Clinical Expertise Areas



# The Clinical Trial Process

(From 6 to 18 months)



Prof Albert Flynn  
Emeritus Professor in Nutrition &  
Former Chair EFSA's NDA Panel



Dr Declan Doogan  
Founder, Portage Pharma Ltd. & Juvenescence Ltd, Former  
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Dr Mary Ellen Sanders  
Executive Science Officer, ISAPP



Prof Ted Dinan, Chairman  
Medical Director, Atlantia, Principal Investigator APC  
Microbiome Ireland & Consultant Psychiatrist

# Scientific Advisory Board

# Sample App

Date of Birth

Choose the Day

dd - mm - yyyy

DAY	MONTH	YEAR
1	2	3
4	5	6
7	8	9
10	11	12
13	14	15
16	17	18
19	20	21
22	23	24
25	26	27
28	29	30
31		

Bowel Movements Today

Bowel Movement # 1

Approximate Time: 17:20

Consistency:

Type 5: Soft blobs with clear-cut edges (passed easily)

Straining with defecation: YES  NO

Delete

Bowel Movement # 2

Approximate Time: 17:20

Consistency:

Type 6: Fluffy pieces with ragged edges, a mushy stool

Cancel Next

Bowel Movements Today

Bowel Movement # 1

Approximate Time:

Choose your consistency

Type 1: Separate hard lumps, like nuts (hard to pass)

Type 2: Sausage-shaped but lumpy

Type 3: Like a sausage but with cracks on its surface

Type 4: Like a sausage of smooth, smooth and soft

Type 5: Soft blobs with clear-cut edges (passed easily)

Type 6: Fluffy pieces with ragged edges, a mushy stool

Type 7: Watery, no solid pieces, Entirely Liquid

Cancel Next

Digestive symptoms – complete in the evening (e.g. bedtime) and score for symptoms throughout the day

Abdominal pain

None Slight Mild Moderate Moderately Severe Severe

Abdominal Discomfort

None Slight Mild Moderate Moderately Severe Severe

Previous Next

Digestive symptoms – complete in the evening (e.g. bedtime) and score for symptoms throughout the day

Bloating

None Slight Mild Moderate Moderately Severe Severe

Flatulence (gas/wind)

None Slight Mild Moderate Moderately Severe Severe

Previous Next

Have you taken your study product today?

YES  NO

Not Applicable

Was it at breakfast time

YES  NO

Not Applicable

Comments: (e.g. any adverse symptoms or medications taken)

Forgot product at breakfast, consumed with lunch.

Previous Next



# Specialised Technologies

## Video Camera Endoscopy (VCE)

- Excellent for Challenge Studies
- Up to 12 hours of HD video to highlight physical changes
- Single use camera
- Small bowel and Large bowel models



## Continuous Glucose Monitoring

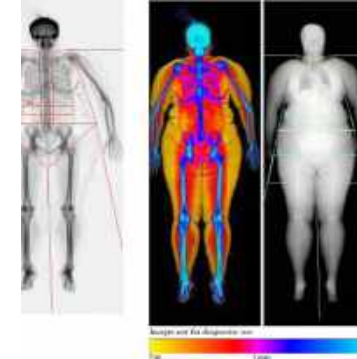
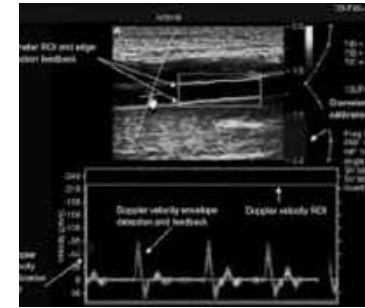
- Type 1 and Type 2 database of subjects
- Can perform real time monitoring of Glucose (CGM) and HbA1c
- Trained team on Oral Glucose Tolerance Testing (OGTT)
- HOMA-IR, ISI etc.



# Other Specialised Technologies



- Cardiorespiratory capacity & Fitness
- Lung Function (VO2 max, sub optimal )
- Physical Activity & Physical Performance
- Body composition measurements (DxA, calipers)
- Muscle strength & endurance (Biodex Isokinetic strength measurement, time to exhaustion, lactate threshold)
- Physical performance (Gait/ speed /Cadence )
- Well-being (hand grip test ,chair stand ,6 minute walk test )
- Dietary Analysis (FFQ and 3 day diet dairy)



- FMD-Ultrasonix technology and trained sonographers, and image specialists
- Radio Opaque markers (WGTT)
- DXA Scans (Muscle /Fat mass, Bone Density, Visceral Fat)
- MRI/X-ray
- Biopsies

# Clinical Study Expertise

## Gastrointestinal health

- Digestive discomfort, Constipation, Bloating, Diarrhoea, Dysphagia, IBS, GERD
- Whole Gut Transit Time: Abdominal scans, Gut microbiota composition, Gut permeability
- Video Capsule Endoscopy (VCE)

## Mental and cognitive health

- Psychological stress, mood, cognition, memory

## Cardiovascular/Metabolic health

- Blood pressure (ABPM), Flow Mediated Dilation (FMD), cholesterol/triglycerides

## Metabolic disorders

- Hyperglycaemia, weight loss (DXA), glucose tolerance, HbA1c, Pre- Diabetes

## Healthy aging

- Sarcopenia, bone health, joint health, osteoarthritis, strength, endurance, mobility, neurodegeneration, cognitive decline

## Liver Function

- Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-alcoholic steatohepatitis (NASH)

## Sports performance

- Muscle mass (DXA), Resistance training, Endurance, Strength, Biodex

## Nutritional health

- Nutrient uptake e.g. protein/amino acid uptake, iron uptake, fatty acid levels (e.g. DHA), vitamin and mineral status

## Immune and inflammatory health

- Allergy, Immune/inflammatory response, IBD, Osteoarthritis, Rhinitis, Upper Respiratory Tract Infection (URTI)

## Infections

- Urinary tract infection (UTI), Upper Respiratory Tract Infections (URTI), *H. pylori*, Antibiotic Associated Diarrhoea (AAD)

## Oral health/oral microbiota

- Dental caries, plaque, tooth mineralisation, Halitosis

## Skin Health

- Trans epidermal water loss (TEWL), Fatty acid analysis

## Why Atlantia?

- ✓ Expertise & proven track record
- ✓ ICH GCP standard trials
- ✓ One company, with multi-centre capability
- ✓ Commitment to delivery on time and on budget
- ✓ Flexible in our approach
- ✓ Offer end to end solutions for the entire clinical study process
- ✓ Data Integrity, Traceability and Accessibility

Get in touch!

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# Bone & Joint Health

	INDICATION	MEASUREMENT
Objective	Physical performance & functional capacity	Hand grip strength (sarcopenia), knee extension & flexion measured by goniometry
	Bone mass and bone mineral density (BMD)	Dual-emission X-ray absorptiometry (DEXA); osteoarthritis: X-RAY & Kellgren-Lawrence Gradient Scale
	Inflammatory markers	Interleukins (IL) -1B1, erythrocyte sedimentation rate (ESR), hsCRP, serum osteocalcin, serum hyaluronic acid (HA), serum keratin sulphate, transforming growth factor beta (TGF-B)
Subjective	Osteoarthritis: knee & joint pain, stiffness, symptoms, sport, recreation & physical function	Bristol Stool Scale, Gastrointestinal Symptom Rating Scale (GSRS), IBS Severity Scoring System (IBS-SSS)
	Pain Intensity	Visual Analogue Scale (VAS); Numeric Rating Scale (NRS); Verbal Descriptive Scale (VDS); McGill Pain Questionnaire
	Physical Performance & functional capacity	Short Physical Performance Battery (SPPB)
	Quality of Life	Short Form (SF) 36 questionnaire; daily or weekly We-diary
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary

# Microbiome Health

MEASUREMENT
Shotgun Metagenomic Sequencing, De Novo Sequencing of Genomes, Flow Cytometry & Fluorescence Activated Cell Sorting (FACS), 16S rRNA sequencing
Metabolomics / Lipidomics, Proteomics, Fatty Acid / Bile Acid Analysis, Transcriptomics, Functional Genomics
Standard & Custom Library Generation, PCR
Dietary Analysis: FFQ, 24 hour recall, 3 day diary

# Cardiovascular Health

	INDICATION	MEASUREMENT
Objective	Physical performance & functional capacity	Exercise / daily activity log; Strength / endurance testing
	Abnormal Body Fat Distribution	Body composition: DEXA; Adipose tissues biomarkers: leptin, adiponectin; Central fat: CT/MRI; Liver fat content: MRS; Weight Management: Dietician
	Insulin Resistance	Elevated fasting glucose: oral glucose tolerance test (OGTT); postprandial insulin; Elevated free fatty acids; Homeostatic Model Assessment of Insulin Resistance (HOMA-IR)
	Hormonal Factors	Leptin, ghrelin, cholecystokinin plasma, glucagon-like peptide (GLP) -1 growth hormones, cortisol
	Vascular Dysregulation	Systolic/diastolic blood pressure (BP); Ambulatory BP; Endothelial function: flow mediated dilation (FMD); ACE inhibitors
	Thrombosis	Fibrinolytic factors (Plasminogen Activating Inhibitor (PAI) -1); Clotting factors (fibrinogen)
	Atherogenic dyslipidaemia	Cholesterol: total, LDL, HDL; Apolipoprotein A1 & B, Omega 3 fatty acids EPA/DHA, conjugated linoleic acid
Subjective	Appetite profile	Visual analogue scale (VAS)diary
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary



# Healthy Ageing

	INDICATION	MEASUREMENT
Objective	Cardiovascular function	Function: oesophageal pH metre, faecal weight and consistency; Transit time: radiopaque pellets; Permeability: lactulose-mannitol tracer test; Motility: gastric scintigraphy; VCE-Video Camera Endoscopy
	Gastrointestinal function	GI transit; bowel function; dysphagia; microbiome diversity
	Physical Activity & performance	Hand grip strength; chair stand test; walking test; agility (chair seat and reach); 2 minute step test
	Biometric & Anthropometric measurements	% lean muscle, bone density, DEXA scan; Measurements: resting heart rate, weight, muscle circumference
	Biological Sample indicators	Plasma essential and non-essential amino acids, total Protein, albumin, serum and urinary urea; serum iron, transferrin saturation, iron binding capacity, ferritin levels; plasma and salivary cortisol, IgA, tryptophan, creatinine; glucose; serum triglyceride; omega-3 fatty acids; oxidative stress measurements
Subjective	GI function	Bristol Stool Scale, Gastrointestinal Symptom Rating Scale (GSRS), IBS Severity Scoring System (IBS-SSS)
	Well-being	Health Status Questionnaire (HSQ), Short Form Health Survey (SF)
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary

# Immune Health

	INDICATION	MEASUREMENT
Objective	Flow Cytometry	Cytokines: Interferons (IFN) e.g. IFN-g, Interleukins (IL) e.g. IL-1B, IL-6, IL-10, Tumour Necrosis Factors (TNF)
	Next Generation Sequencing	Granulocytes: Neutrophils, Basophils, Eosinophils
	PCR	Glucocorticoid: cortisol; Immunoglobulins (Ig) e.g. IgA, IgE
	Multiplexed Immunoassay	Shotgun sequencing, functional genomics, metabolomics, transcriptomics
	ELISA	High-sensitivity C-reactive protein (hsCRP)
	Single Cell Analysis e.g. Proteomics	Monocytes / Macrophages
Subjective	Dietary Analysis	FFQ, 24 hour recall, 3 day diary

# Metabolic Health

	INDICATION	MEASUREMENT
Objective	Physical performance & functional capacity	Exercise / daily activity log; Strength / endurance testing
	Abnormal Body Fat Distribution	Body composition: DEXA or Tanita anthropometric measurements (waist circumference, calliper skin fold thickness, body composition analyser (bioimpedance); Adipose tissues biomarkers: leptin, adiponectin; Central fat: CT/MRI; Liver fat content: MRS; Weight Management: Dietician
	Insulin Resistance	Elevated fasting glucose: oral glucose tolerance test (OGTT); postprandial insulin; Elevated free fatty acids; (HOMA-IR)
	Hormonal Factors	Leptin, ghrelin, cholecystokinin plasma, glucagon-like peptide (GLP) -1 growth hormones, cortisol
	Vascular Dysregulation	Systolic/diastolic blood pressure (BP); Ambulatory BP; Endothelial function: flow mediated dilation (FMD); ACE inhibitors
	Inflammation	High sensitivity C-reactive protein (hsCRP); Cytokines: TNF alpha, interleukin-6; Bradykinin;
	Thrombosis	Fibrinolytic factors (Plasmalogen Activating Inhibitor (PAI) -1); Clotting factors (fibrinogen)
	Atherogenic dyslipidaemia	Cholesterol: total, LDL, HDL; Apolipoprotein A1 & B, Omega 3 fatty acids EPA/DHA, conjugated linoleic acid
Subjective	Appetite profile	Visual analogue scale (VAS)diary
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary



MEASUREMENT
Shotgun Metagenomic Sequencing, De Novo Sequencing of Genomes, Flow Cytometry & Fluorescence Activated Cell Sorting (FACS), 16S rRNA sequencing
Metabolomics / Lipidomics, Proteomics, Fatty Acid / Bile Acid Analysis, Transcriptomics, Functional Genomics
Standard & Custom Library Generation, PCR
Dietary Analysis: FFQ, 24 hour recall, 3 day diary

# Nutritional Health

	INDICATION	MEASUREMENT
Objective	Cardiovascular & Metabolic Health	Blood Pressure (BP); Ambulatory BP; Endothelial function e.g. flow-mediated dilation (FMD); Inflammatory biomarkers: interleukine-6, C-reactive protein; blood cholesterol: total, LDL, HDL
	Physical Activity & performance	Aerobic capacity/VO2 max, muscle mass / strength
	Body composition measurements	% lean muscle, bone density, using DEXA scan; Biometric & Anthropometric Measurements: resting heart rate, weight, muscle circumference
	Nutrient Analysis	Plasma essential and non-essential amino acid; plasma ketones; plasma creatine and urinary nitrogen; plasma glucose, insulin, serum triglycerides, serum and urinary urea, urinary ammonia, serum and urinary protein levels, metabolomics, lipidomics, proteomics
Subjective	Physical performance	International Physical Activity Questionnaire (IPAQ)
	Well-being	WHO 5 well being index
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary



# Physical Activity & Sports Health

	INDICATION	MEASUREMENT
Objective	Cardiorespiratory capacity & Fitness	Cardiopulmonary Exercise Testing (CPET), respiratory oxygen uptake (VO <sub>2</sub> ), carbon dioxide production (VCO <sub>2</sub> ), maximal aerobic capacity (VO <sub>2</sub> max), anaerobic threshold, fat and carbohydrate metabolism, energy cost of exercise, resting metabolic rate can be assessed
	Lung Function	Pulmonary Function Tests (PFT) peak expiratory flow (PEF), forced vital capacity (FVP) and forced expiratory volume (FEV) using a spirometer
	Physical Activity & Physical Performance	Jumping height, 1 repetition maximum weight lift (1RM), timed get up and go, chair stand 6 min walking test, stair climb power test, gait speed, flexibility and range of motion, economy of motion, muscle fatigue, acceleration (accelerometer)
	Body composition measurements	% lean muscle, bone density, using DEXA scan; Biometric & Anthropometric Measurements: resting heart rate, weight, muscle circumference
	Muscle strength & endurance	Biodex Isokinetic Test measures isokinetic (both eccentric and concentric) function and isometric strength on major muscle groups, handgrip strength (arm curl with hand weight); Endurance Capacity: lactate threshold, multi-sprint endurance
Subjective	Physical performance	International Physical Activity Questionnaire (IPAQ)
	Well-being	Health Status Questionnaire (HSQ), Short Form Health Survey (SF)
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary

# Skin Health

	INDICATION	MEASUREMENT
Objective	Epidermal Hydration	Cornometer; Skin surface pH: Skin pH Meter; Transepidermal Water Loss (TEWL): Tewameter; Erytherma & Melanin: Mexameter; Skin topography (wrinkle area & depth): Visiometer; Skin firmness/elasticity: Cutometer; Minimal Erytherma Dose (MED):Durham Erytherma Tester
	Profiling of skin microbiota and lipids	Sequencing, Transcriptomics, Functional Genomics, Flow Cytometry, PCR, Lipidomics
Subjective	Measure of pruritis	5-Dimension (Degree, Duration, Direction, Disability & Distribution) Itch Scale
	Skin dryness & presence of skin tears	Overall Dry Skin (Xerosis) Score (ODS); Skin Tear Audit Research (STAR) classification system
	Well-being	WHO-Five Well-being Index (WHO-5)
	Self-assessment of sleep quality	Richards-Campbell Sleep Questionnaire (RCSQ)
	Dietary Analysis	FFQ, 3 day diary

# Stress & Cognitive Health

	INDICATION	MEASUREMENT
Objective	Changes in biological stress indicators	Salivary and plasma cortisol; IgA; tryptophan; heart rate
Subjective	Cognitive Function	Standardised cognitive test battery e.g. Cogstate, CANTAB; mini-mental state examination (MMSE)
	Cognitive development in children	Age specific neurodevelopment tests
	Anxiety & Depression	Hamilton Anxiety Rating Scale (HAM-A); Beck depression inventory; Hamilton Depression Rating Scale (HAM-D); Trier social stress test (TSST)
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary



# Women Health

	INDICATION	MEASUREMENT
Objective	Cardiovascular health	Blood Pressure (BP); Ambulatory BP; Endothelial function e.g. flow-mediated dilation (FMD)
	Gastrointestinal health	GI transit; bowel function; microbiome diversity
	Physical Activity & performance	Aerobic capacity/VO2 max; muscle max/strength
	Body Composition measurements	% lean muscle, bone density, DEXA scan; Measurements: resting heart rate, weight, muscle circumference
	Vaginal infections (VI) follow up	Amsel’s criteria and Nugent scoring system used as diagnostic method and primary outcomes evaluation, reduction in episodes of VI (compared to placebo), Severity of VI symptoms , Duration of VI symptoms, Microbiological profiling (Vaginal Microbiome)
	Biological Sample indicators	Inflammatory biomarkers; plasma essential and non-essential amino acids, total protein, albumin, serum and urinary urea; plasma and salivary cortisol, IgA, tryptophan (stress indicators), creatinine; glucose; serum triglyceride; omega-3 fatty acids; oxidative stress measurements
Subjective	GI health	Gastrointestinal Symptom Rating Scale (GSRS)
	Physical Activity	International Physical Activity Questionnaire (IPAQ)
	Anxiety & Sleep Quality	Hamilton Anxiety Rating Scale (HAM-A)
	Well-being	Health Status Questionnaire (HSQ), Short Form Health Survey (SF)
	Dietary Analysis	FFQ, 24 hour recall, 3 day diary