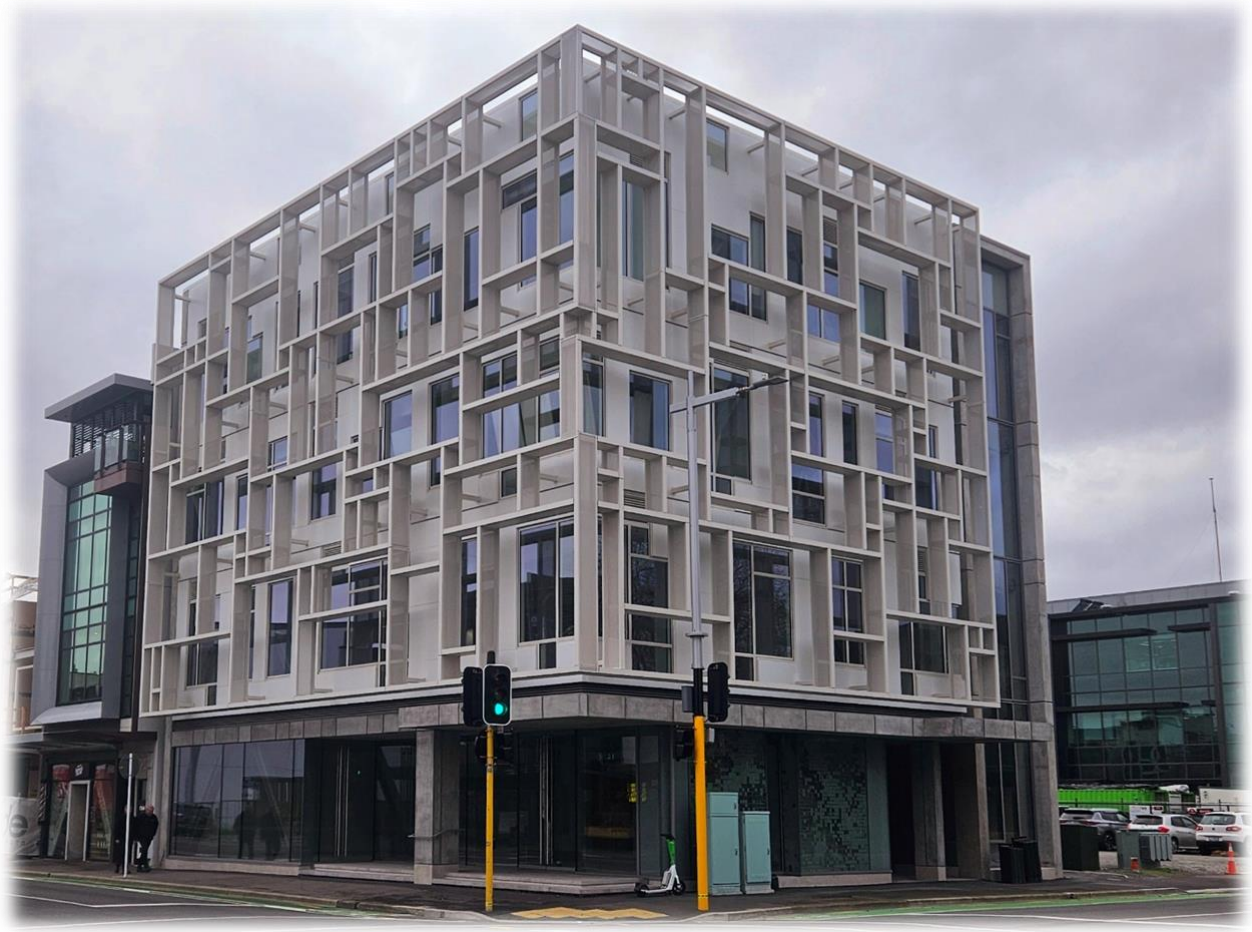
CGM Research Trust



Research Portfolio

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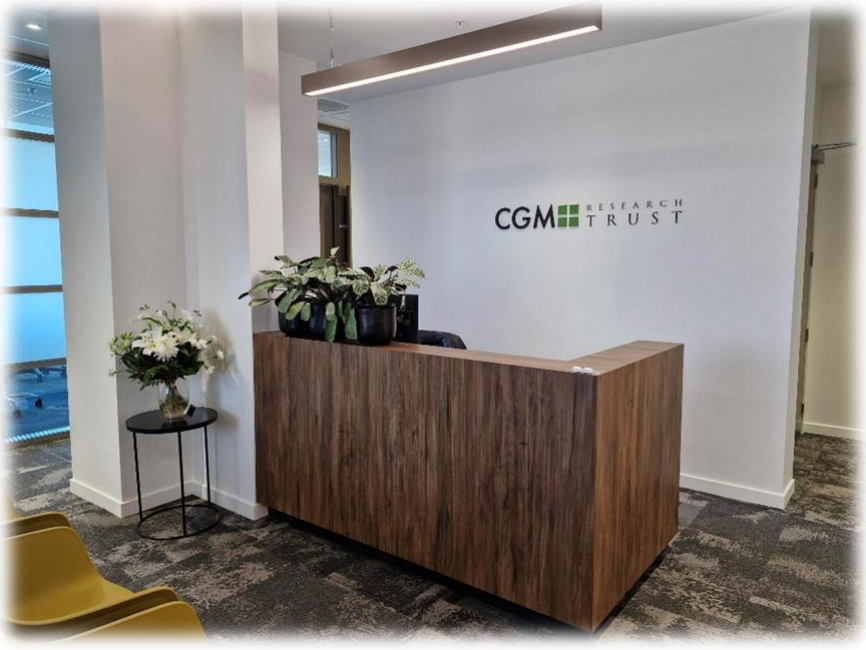

Therapeutic Area	Study
Bone Health	A Multicentre, International, Randomized, Double-blind, Alendronate-controlled Study to Determine the Efficacy and Safety of study drug in the Treatment of Postmenopausal Women with Osteoporosis Phase III randomised double blind, placebo-controlled study plus extensions extension to examine safety, tolerability & efficacy of Odanacatib 50 mg once weekly to decrease risk of # in postmenopausal osteoporotic women treatment with Vit D & calcium. Also assess long term effects on BMD at lumbar spine and hip sites, Determine incidence of fracture & effect on height A Study of Raloxifene HCl and Placebo in the Prevention of Invasive Breast Cancer in Post-menopausal women with Osteoporosis Prospective Observational Study Post-Menopausal Females with Osteoporosis taking Forteo A Phase II randomised, double-blind, placebo and active controlled, dose-range finding study to evaluate the effects of study drug on bone mineral density in the treatment of Osteoporosis in postmenopausal women previously treated with an oral bisphosphonate A Double-Blind, Randomised, Placebo-controlled, Multicenter 4-week Study to Assess the Effect of Alendronate 70mg and Vitamin D3 2800 IU Once Weekly on Fractional Calcium Absorption in Postmenopausal Osteoporotic Women A 24-Month, Double Blind, Placebo-Controlled, Multicentre Study to Evaluate the Safety and Efficacy of Oral Alendronate Sodium for the Treatment of Osteoporosis in Men Efficacy and Safety of study drug in the treatment of men with osteoporosis A randomised, double-blind, placebo-controlled study to assess the safety, tolerability and efficacy of a cathepsin-K-Inhibitor in the treatment of postmenopausal women with osteoporosis and extensions A Retrospective Audit on the Effect of Rocaltrol on Bone Mineral Density in Osteoporosis and the Determination of their Vitamin D Receptor Status MK217 Three Year Treatment for the Prevention of Bone Loss During Early Post Menopause (MSD) Alendronate Treatment study – A Randomised, Double Blind, Multi-Centre Study to Compare the Safety and Efficacy of Oral Alendronate Sodium 35mg Twice -Weekly, 70mg Once -Weekly, and 10mg Daily for the Treatment of Osteoporosis in Postmenopausal Women A Randomised, Double-Blind, Placebo Controlled, Multi centre Parallel group study to determine the safety and efficacy of Risedronate in the Treatment of Osteoporosis in Elderly Women Continuing Outcomes Relevant to Evista® (CORE) A study of Raloxifene HCL and Placebo in the Prevention of Invasive Breast Cancer in Postmenopausal Women with Osteoporosis Effects of Arizofexene on Vertebral fracture incidence and incidence of breast cancer in Post-Menopausal with Osteoporosis or low Bone Mineral Density without Osteoporosis Alendronate Prevention Study- A Randomised, Double-Blind, Multi-Centre Study to Compare the Safety and Efficacy of Oral Alendronate Sodium 35 mg once-Weekly and 5mg Daily for the Prevention of Osteoporosis in Postmenopausal Women Medication Use Patterns, Treatment Satisfaction, and Inadequate Control of Osteoporosis Study an Asia Pacific study of postmenopausal women treated for osteoporosis in clinical practice Randomised Trial of Genetic Testing and Targeted Zoledronic acid Therapy to Prevent SQSTM1 Mediated **Paget's Disease** (Zoledronate in the Prevention of Paget's) A Six Month Multicentre, Double – Blind, Randomised, Active - Controlled Trial to Evaluate the Safety, Efficacy and Tolerability of Alendronate 280 – mg Oral Buffered Solution Once Weekly in Patients with **Paget's Disease** of Bone A Prospective, multi-centre, randomised comparative study of 3 Hip Stems implants to access fit, clinical outcomes and patient satisfaction and osteointegration

Bone Health	Spinal Cord Injury Prospective randomised double blind, placebo-controlled study to compare safety & efficacy of sub-cut 6monthy Denosumab 60mg in acute spinal cord injury Historical Assessment of Risk Factors in Screening for Osteopenia in a Normal Caucasian population The Effects of Dairy Supplementation on Bone Density in Teenage School Girls Investigations of the Effects of Cytotoxic Chemotherapy on Bone Mineral Content of Young Men A Double-Blind Comparison Of Aredia versus Nandrolone Deconate versus Placebo on Bone Density, Respiratory and Muscle Function in Steroid Dependent Asthmatics A Prospective, Randomised, Double Blind, Placebo Controlled Study to Compare the Safety And Efficacy Of Oral Alendronate Sodium 70mg Once Weekly In Acute Spinal Cord Injury In Young Males And Females Effects of Age, Sex and Risk Factors on Bone Density at the Hip and Spine in a Normal New Zealand Population
Cardiovascular	A Multi centre, Double Blind, Randomised, Parallel- Group study to Investigate the Incidence of **Cough** in Patients Receiving Losartan 50mg. Lisinopril 20mg or Hydrochlorothiazide 25mg Who Have Reported Cough with an Angiotensin Converting Enzyme Inhibitor. (MSD) The Effect of NSAIDS on ACE induced **Cough** A Randomised, Double-Blind, Multi-centre study of the Safety and Antihypertensive Efficacy of the Losartan 50mg/ Hydrochlorthiazide (HCTZ) 12.5 mg Combination Compared to the Captopril 50mg/HCTZ 25 mg Combination in Elderly and Younger Patients with Mild to Moderate **Hypertension** (MSD) Double Blind Placebo Controlled Cross over Pilot study to compare the effects of Lacidipine with that of placebo on vasoactive hormones A Double-Blind, Active, Crossover Study Assessing the Effect of beta Glucan on Blood Lipids and Body Composition in Healthy Subjects A pilot study to test a new method of reducing the risk of stroke from aortic repair - Intervention with Cerebral Embolic Protection in Thoracic endovascular aortic repair (TEVAR) A randomised controlled trial
Vaccines	A double blind, randomised, placebo controlled, parallel group, multicentre study to investigate the efficacy and safety of inhaled zanamivir 10mg administered twice daily for five days in the treatment of symptomatic **influenza** A and B viral infections in subjects aged 65 years and over A Phase II, Observer-Blind, Randomised, Single-Centre Study to Evaluate Safety, Tolerability and Immunogenicity of a Single Intramuscular Dose of Trivalent Subunit **Influenza** Vaccine produced either in Mammalian Cell Culture or in Embryonated Hen Eggs, in Healthy Adult Subjects A Double Blind, Stratified, Randomised, Placebo-Controlled Study of study vaccine in the Treatment of **Influenza** in Elderly Patients A Prospective, Multi-Centre, Double-Blind, Randomised Comparative Study to Evaluate the Efficacy, Safety and Tolerability study drug Versus Cefepime in the Treatment of Hospital-Acquired **Pneumonia** in Adults A Phase 3, Randomized, Double-blind, Active Comparator-controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in **Pneumococcal Vaccine**-naïve Adults 18 to 64 years of Age With Increased Risk for Pneumococcal Disease
Neurological	An Open and Uncontrolled Long-Term Safety and Tolerability Study of Sinemet CR in Patients with Mild to Moderate **Parkinson's Disease** Perispinal Etanercept to Improve Stroke Outcomes. A Prospective Phase 2b randomised double-blind trial to determine safety & efficacy Etanercept to improve QoL 28 days post treatment

Inflammatory	Phase 3 Randomized, Double Blind Study of The Efficacy and Safety Of 2 Doses of study drug compared To Methotrexate In Methotrexate Naïve Patients With **Rheumatoid Arthritis** Phase III multi-Centre, open label, study to access the efficacy and safety of an engineered human anti-TNF PEG conjugate, as additional medication to methotrexate, in treatment of signs & symptoms and preventing structural changes in patients with active **Rheumatoid Arthritis** Phase 3 Randomized, Double-blind, Study to Determine the Efficacy and Safety of study drug compared to Methotrexate in Methotrexate Naïve patients with RA A randomized, double blind trial for the safety of Anti-TNF monoclonal antibody in combination with Methotrexate compared to methotrexate alone in patients with **Rheumatoid Arthritis** on standard disease modifying anti-rheumatic drug background therapy A phase 3, randomized, double-blind study of the efficacy and safety of 2 doses of a study drug compared to methotrexate in methotrexate naive patients with **Rheumatoid Arthritis** A Phase II, randomized, Double-Blind Study to Evaluate the Effects of study drug, a humanized Monoclonal Antibody to Integrin Alpha V Beta 3, on Disease Activity and Progression of Joint Damage in Patients with Active **Rheumatoid Arthritis** Sub -Optimally Responding to Methotrexate Multi-center, randomized, double blind placebo controlled, parallel group, phase II clinical trial to access the efficacy and safety of subcutaneous study drug in subjects with **Rheumatoid Arthritis** A multi-center, uncontrolled extension study evaluating efficacy and safety of SARILUMAB on top of DMARDs in patients with active **Rheumatoid Arthritis** (RA) A multicenter, randomised, double-blind, placebo-controlled trial of a fully human Anti-TNF a monoclonal antibody, administered intravenously, in subjects with active **Rheumatoid Arthritis** despite Methotrexate therapy Phase III multicenter, double blind, placebo-controlled, parallel group 52–week study to assess the efficacy and safety of 2 dose regimens of lyophilised CD870 given subcutaneously as additional medication to methotrexate in the treatment of signs and symptoms and preventing structural damage in patients with active **Rheumatoid Arthritis** who have an incomplete response to methotrexate A randomised, Double-Blind, International Study to Evaluate the Efficacy and Safety Of Various Re-treatment Regimens Of Rituximab In Combination With Methotrexate In **Rheumatoid Arthritis** patients With An Inadequate Response To Methotrexate A multi-center randomised, double-blind, placebo-controlled, dose-ranging study to evaluate the safety, tolerability, efficacy, pharmacokinetics and immunogenicity of ART621 following multiple dose administration for 3 months in patients with **Rheumatoid Arthritis** concomitantly taking methotrexate A Phase 3 Multicentre, Randomized, Double-blind, Placebo-controlled trial of a Fully Human anti-IL Monoclonal Antibody, Administered subcutaneously in Subjects with Active **Psoriatic Arthritis** A Phase 2, randomized, double-blind placebo-controlled study to test the efficacy and safety of KPL 301 in **Giant Cell Arteritis** A Phase III trial in patients with moderate to severe **PsA** utilizing Risankizumab who have been unresponsive or had inadequate response to csDMARDS &/or Biologics A Phase III trial in patients with moderate to severe **PsA** utilizing Risankizumab who have been unresponsive or had inadequate response to at least 1 csDMARD Phase III safety & Efficacy study of Upadacitinib in Subjects with **Giant Cell Arteritis** Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects with **Polymyalgia Rheumatica** (PMR) Dependent on Glucocorticoid Treatment A randomized, parallel-group, double-blind, placebo-controlled, multicenter Phase III trial to investigate the efficacy and safety of secukinumab 300 mg and 150 mg administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, in patients with **Giant Cell Arteritis** (GCA) (GCAptAIN)
Gastrointestinal	A double-blind, placebo controlled pilot study on the effect of **supplementation** of a flavonoid extract on quality of life, neuromuscular balance, vision and the markers of oxidative damage on healthy elderly participants

	A multicentre, randomised, parallel-group, active and placebo-controlled, double-blind study conducted under in-house blinding conditions to determine the incidence of Gastroduodenal ulcers in patients with Osteoarthritis after 12 weeks of treatments with placebo, low dose aspirin, study drug of Ibuprofen Famotidine in the Treatment of gastric and Duodenal Ulcers A multicentre, randomised, parallel-group, active and placebo-controlled, double-blind study conducted under in-house blinding conditions to determine the incidence of Gastroduodenal ulcers in patients with Osteoarthritis after 12 weeks of treatments with placebo, low dose aspirin, study drug of Ibuprofen Famotidine in the Treatment of gastric and Duodenal Ulcers Phase 11B to evaluate efficacy and tolerability of study drug in Coeliac disease on subjects with symptoms on gluten free diet A phase II, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and tolerability of study drug in celiac disease subjects experiencing symptoms despite gluten-free diet with gluten challenge An international, multicentre, randomised, double-blind, parallel-group controlled trial evaluating the safety, effeteness and PK of Bupivacaine in patients undergoing elective major abdominal surgery
Respiratory	A multi-centre, multinational, randomized, double-blind controlled clinical study of the efficacy and safety of oral telithromycin 800 mg once a day for 5 days versus azithromycin (500 mg OAD. day 1 then 250 mg OAD. for 4 days) in the treatment of acute exacerbation of chronic bronchitis in adult outpatients with chronic obstructive pulmonary disease Comparison of the Efficacy and Adverse Effect Profile of Oral Cefpodoxime Proxetil 200mg bid And Usual Antibiotic Therapy in Hospitalised Patients with Pneumonia and exacerbations of Chronic Bronchitis / COPD A Double-Blind Comparison Of Aredia versus Nandrolone Deconate versus Placebo on Bone Density, Respiratory and Muscle Function in Steroid Dependent Asthmatics A Multi centre, Double Blind, Randomised, Parallel- Group study to Investigate the Incidence of **Cough** in Patients Receiving Losartan 50mg. Lisinopril 20mg or Hydrochlorothiazide 25mg Who Have Reported Cough with an Angiotensin Converting Enzyme Inhibitor. (MSD) The Effect of NSAIDS on ACE induced **Cough**
Sarcopenia	Phase1 Study Double blind, placebo-controlled study to assess the safety & efficacy of study drug to increase muscle mass in health postmenopausal women. A Phase IIa Randomized, Placebo-Controlled Clinical Trial to Study the Efficacy and Safety of a study drug in Patients with **Sarcopenia** A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of Intravenous FDY-5301 in Tourniquet Induced **Sarcopenia** A double-blind, placebo controlled pilot study on the effect of **supplementation** of a flavonoid extract on quality of life, neuromuscular balance, vision and the markers of oxidative damage on healthy elderly participants
Pain	Clinical Protocol For A Multicentre, Double-blind, Double-Dummy, Randomised Study of the Analgesic Efficacy and Safety of Valdecoxib Compared to Diclofenac Sodium In Patients Undergoing Knee Arthroscopy Procedure For Anterior Cruciate Ligament Reconstruction A Multi-Center, Prospective, Observational, Extension Trial Following DURECT Protocol C803-017 to Investigate the Long-term Safety of SABER™-Bupivacaine Following Arthroscopic Shoulder Surgery Randomized, 16-Week, Multi-Phase, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of a DMAB as Adjunctive Therapy in Subjects with Signs and Symptoms of Osteoarthritis of the Hip or Knee

Pain	A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Effectiveness of Extoricoxib in Patient's with OA & RA Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with study drug Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain A Randomized Double-Blind, Placebo- and Active-Control, Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee A Randomized, Double-blind, Active-And Placebo-Controlled, Parallel Group, Multicentre Study to Evaluate The Efficacy And Safety of Multiple Doses of CG5503 Immediate-Release Formulation In Subjects Awaiting Primary Joint Replacement Surgery for End-Stage Joint Disease An international, multicentre, randomised, double-blind, parallel-group controlled trial evaluating the safety, effeteness and PK of Bupivacaine in patients undergoing elective major abdominal surgery A Multi-Centre, Prospective, Observational, Extension Trial to Investigate the Long term Safety of -Bupivacaine Following Arthroscopic Shoulder Surgery Phase 2b Placebo and Active Comparator-Controlled, Parallel-Group, 6-week, Double-Blind Study, Conducted Under In-House Blinding Conditions, to Assess the Safety and Efficacy of study drug (MK-0966) Versus Ibuprofen in Patients with Osteoarthritis of the Knee and Hip. A Phase 3, open-label, multiple-dose, single-arm exposure study of Maxigesic IV in patients with acute pain following orthopaedic, general and plastic surgery (AFT-MX11). Phase1b Investigating PP353 Intradiscal antibiotic in chronic low back pain 5yr Phase IIb efficacy safety and tolerability of intra-articular study drug in symptomatic knee OA Phase II study drug for symptomatic knee OA Nanobody targeting ADAMTS-5 to reduce cartilage degeneration and Pain
New Device Trials	Phase I prospective, multicentre, single arm trial to investigate the safety and feasibility of the Precicetm 8.5 mm intramedullary limb lengthening system An Evaluation of the Safety and Effectiveness of the DePuy Minimally Invasive Knee Replacement and Instruments Assessing the efficacy and tolerability of a new ostomy device compared with standard device Assessment of Wear Time of One Piece Closed Ostomy Pouches Constructed with Barrier PL-0337 Various Faceplate Designs using Ostomate Volunteers Use of the iDXA to evaluate prosthesis effectiveness in Orthopedic Subjects who Undergo an Oxford Uni-Compartmental Knee replacement Precision of the iDXA in measuring bone density around the tibial component of the Oxford Uni-compartmental knee prosthesis Cross-sectional study of bone density around the tibial component of the Oxford Uni-compartmental knee prosthesis 2 years post-operatively Prospective study of bone density around 3 different un-cemented acetabular components in total hip Arthroplasty A Multi-centre, Randomized, Double-blind, Placebo-controlled Study of AMG 785 in Skeletally Mature Adults with a Fresh Unilateral Tibial Diaphyseal Fracture Status Post Definitive Fracture Fixation with an Intramedullary Nail
Ophthalmology Studies	Phase 11 Intravitreal APL-2 therapy in subjects with Geographic Atrophy FILLY Phase 3 open-label extension Pegcetacoplan in subjects with GA secondary to age related Macular degeneration 3202 A Phase 3, Multi-centre, Randomized, Quadruple-masked, Placebo controlled Study of Batoclimab for the Treatment of Participants with Active Thyroid Eye Disease

Ophthalmology Studies	3203 Open- Label Extension Double masked randomised Vehicle controlled 12 month parallel comparison of Safety & Efficacy CBT-001 Phase 3 Clinical Trial to Evaluate Subcutaneous Injections of Elampretide in Subjects with Age-Related Macular Degeneration
Alzheimer's Dementia **&** **Mild Memory Loss**	Randomised, double blind placebo controlled multi-centre registration to evaluate the efficacy and safety of study drug in Patient with mild Alzheimer's disease receiving Acetylcholinesterase and/or Memantine Randomized, Double-Blind, Placebo Controlled, Multi-centre registration Trial to Evaluate the Efficacy and Safety of study drug in patients with mild AD receiving Acetylcholinesterase Inhibitors and/or Memantine A randomised, multi-centre, double blind placebo controlled 18motnth study of the efficacy of Study Drug in Patients with dementia of Alzheimer's type A 30-week, Multicentre, Double Blind, Placebo-Controlled evaluation of the Safety and Efficacy of E2020 in Patients with Alzheimer's Disease Efficacy and Safety different dose strengths of free base study drug for 12 Weeks in a Double-Blind, Randomised, Placebo-Controlled Parallel Group Comparison in Patients with Mild to Moderate Dementia of Alzheimer Type. Now in open-label extension A Randomised, Double-Blind, Placebo-Controlled Evaluation of the Efficacy of memantine on Functional communication in patients with Alzheimer's disease A multicentre, randomised, double-blind, placebo-controlled, dose ranging study to evaluate AIT-082 in patients with probable Alzheimer's Disease of mild to moderate severity Placebo controlled evaluation of galantamine in the treatment of Alzheimer's disease: safety and efficacy of a controlled release formulation GAL INT 2 and GAL INT 8 followed by - Long-term safety and efficacy of synthetic galantamine in the treatment of Alzheimer's Disease A Randomised Double-Blind Placebo-Controlled Trial Tt Evaluate the Efficacy and Safety Of Galantamine In Subjects With Mild Cognitive Impairment (MCI) Clinically At Risk For Development Of Clinically Probable Alzheimer's Disease GAL-int-18 and extension GAL IMCI 301 Phase 2 Multiple dose, multicentre randomised, double blind, placebo-controlled study to evaluate the efficacy and safety of a study drug in subjects with Early Alzheimer's Disease A randomized, multicentre, double-blind, placebo-controlled, 18-month study of the efficacy of Xaliproden in patients with mild-to-moderate Alzheimer's disease A randomized, multicentre, double-blind, placebo-controlled, 18-month study of the efficacy of Xaliproden in patients with mild-to-moderate Alzheimer's disease Protocol A multi-centre open label extension study to assess the long-term safety and efficacy of Rosiglitazone (extended release tablet) in subjects with mild to moderated Alzheimer's disease A Parallel-Group, Double-Blind, Long Term Safety and Efficacy Trial of study drug in Subjects with Amnestic Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal AD) Efficacy of 15 mg and 50 mg of S 18986 on cognitive symptoms in Mild Cognitive Impairment patients treated over a 12-month oral administration period. An international multicentre, 3 parallel groups, randomised, double blind, placebo-controlled phase II study A 24-week double-blind, randomised, placebo-controlled, parallel-group dose-ranging study to investigate the effects of rosiglitazone (extended release tablets) on cognition in subjects with mild to moderate Alzheimer's disease A phase II a/b double-blind, randomised, placebo-controlled, linear trend design dose-ranging study to investigate the effects of 24 weeks of monotherapy with SB-742457 on cognition in subjects with mild to moderate Alzheimer's disease

Alzheimer's Dementia **&** **Mild Memory Loss**	A Randomised, Placebo Controlled Parallel Group, Double Blind Efficacy and Safety Trial for MK-8931 with Long-term Double Blind Extension in Subjects with Mild to Moderate Alzheimer's Disease A Phase III, Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Clinical Trial to Study the Efficacy and Safety of study drug in Subjects with Amnestic Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal AD) Phase III randomised placebo-controlled study with Suvorexant for treatment of Insomnia in AD A Phase 2 Multiple Dose, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABBV-8E12 in Subjects with Early Alzheimer´s Disease. Phase 2 extension of Study M15-566 evaluating the long-term safety and tolerability of ABBV-8E12 in subjects with early Alzheimer's disease A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of AL002 in Participants with Early Alzheimer's Disease Phase 11b Dose finding study to evaluate safety and efficacy of ABBV-552 in Mild AD