

	Title	Lead Author	Authors	WP
1	A regulators' challenge: the transfer of new scientific knowledge into regulatory practice. The example of PROTECT.	EMA	Kurz X., Arlett P.	WP1
2	Scientific Validation in an Era of Rapid Decision Cycles: Differing Views on the Implementation of Results from Regulatory Science.	EMA	Kurz X., Dal Pan G., Martin D., Chan K.A., Roddam A., Leufkens H.	WP1
3	Instrumental Variables Analysis Using Multiple Databases: an Example of Antidepressants Use and Risk of Hip Fracture.	UU	M.J. Uddin, R.H.H. Groenwold, A de Boer, H Gardarsdottir, E. Martin, G. Candore, S.V. Belitser, A.W. Hoes, K.C.B. Roes, O.H. Klungel	WP2 (WG2)
4	Evaluating Different Preference Based Instrumental Variables in Two Primary Care Databases: a Study of Beta2-Agonist Use and Risk of Myocardial Infarction.	UU	M.J. Uddin, R.H.H. Groenwold, A. de Boer, A. Afonso, P. Primatesta, C. Becker, S.V. Belitser, A.W. Hoes, K.C.B. Roes, O.H. Klungel	WP2 (WG2)
5	Understanding inconsistency in the results from observational pharmacoepidemiological studies: the case of antidepressant use and risk of hip fracture.	UU	V. Abbing-Karahagopian, P. Souverein, E. Martin, C. Huerta, F. de Abajo, H. Leufkens, G. Candore, Y. Alvarez, J. Slattery, M. Miret, G. Requena, M. Gil, R. Groenwold, R. Reynolds, R. Schlienger, M. de Groot, O.H. Klungel, T. van Staa, T. Egberts, M.L. De Bruin and H. Gardarsdottir.	WP2 (WG1)
6	Association between inhaled long-acting beta-2-agonists and the risk of acute myocardial infarction: a methodological comparison of two databases.	UU	Afonso A., Schmiedl S., Becker C., Primatesta P., Plana E., Souverein P., Korevaar J.C., Hasford J., Reynolds R., de Groot M.C.H., Schlienger R., Klungel O., Rottenkolber M.	WP2 (WG1)
7	Risk of hip fractures associated with benzodiazepines: common methodology but different results in a multi-site cohort study. The PROTECT project.	AEMPS	G. Requena, C. Huerta, H Gardarsdottir, M Miret, E Martín, PC Souverein, C Schneider, R González-González, A Bate, Y Alvarez, A Alvarez, D Montero, LA García-Rodríguez, R Reynolds, R Schlienger, MCH de Groot, OH Klungel and F de Abajo	WP2 (WG1)
8	Changes in drug prescriptions after the SMART trial – secondary data analysis of Bavarian asthma patients.	LMU	Rottenkolber M, Fischer R Ibáñez L, Fortuny J, Klungel O, Reynolds R, Gerlach R, Tauscher M, Thürmann P, Hasford J, Schmiedl S	WP2 (WG3)

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9	Understanding inconsistent results from observational pharmacoepidemiological studies: the case of antidepressant use and risk of hip fracture.	UU	H Gardarsdottir, V Abbing-Karahagopian, P Souverein, E Martin, C Huerta, F de Abajo, H Leufkens, G Candore, Y Alvarez, J Slattery, M Miret, G Requena, M Gil, R Groenwold, R Reynolds, R Schlienger, M de Groot, OH Klungel, T van Staa, T Egberts, ML De Bruin	WP2
10	Impact of varying control moment selection in a case-crossover (CCO) study on antidepressant drug (AD) use and hip/femur fracture (HFF) in PROTECT.	UU	Mark C.H. De Groot, Svetlana V. Belitser, Patrick C. Souverein, Helga Gardarsdottir, Rolf H.H. Groenwold, Gianmario Candore, Yolanda Alvarez, Raymond G. Schlienger, Robert Reynolds, Olaf H. Klungel	WP2 (WG1)
11	No impact of adjusting for lifestyle factors or general practice on risk estimates for the association between antidepressants and hip/femur fracture.	UU	P.C. Souverein, M.C.H. de Groot, E. Martin, C. Huerta, G. Candore, Y. Alvarez, J. Slattery, J. Logie, G. Requena, M. Gil, F. de Abajo, R. Reynolds, R.G. Schlienger, O.H. Klungel and H. Gardarsdottir	WP2 (WG1)
12	Do case-only designs yield consistent results between them and across different databases (DBs)? Hip fractures associated with benzodiazepines (BZD) as a case study.	AEMPS	G Requena, J Logie, E Martín, C Huerta, R González-González, N Boudiaf, A Alvarez, A Bate, LA Garcia-Rodríguez, R Reynolds, R Schlienger, M de Groot, OH Klungel, F de Abajo and I Douglas	WP2 (WG1)
13	Risk of hip fractures associated with benzodiazepines: applying common protocol to a multi-database nested case-control study. The PROTECT project.	AEMPS	G Requena, John Logie, R González-González, H Gardarsdottir, A Afonso, PC Souverein, E Martín, N Boudiaf, C Huerta, A Bate, Y Alvarez, M Gil, LA Garcia-Rodríguez, R Reynolds, R Schlienger, MCH de Groot, OH Klungel and F de Abajo	WP2 (WG1)
14	Impact of methodological choices on findings from pharmacoepidemiological studies: final results of the IMI-PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) project.	UU	O.H.Klungel, M.C.H. de Groot, H. Gardarsdottir, R. Brauer, L. Grimaldi-Bensouda, C. Gasse, X. Kurz, R. Reynolds.	WP2+WP6

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15 Calcium channel blockers and cancer risk using the UK CPRD.	Laser	Grimaldi-Bensouda L, de Groot M.H.C., Hesse U, Reynolds R, Klungel O, Rossignol M.	WP2 (WG1)
16 The risk of acute liver injury among users of antibiotic medications: The results of a nested case-control study using European outpatient healthcare data.	Amgen-LSTHM	Ruth Brauer, Ian Douglas , Luis Alberto Garcia Rodriguez, Andrew Bate, Liam Smeeth, Robert Reynolds, Olaf Klungel and Ana Ruigómez	WP2 (WG1)
17 Antidepressant Use and the Risk of Hip Fracture: a Comparison of Marginal Structural Models and Conventional Regression Methods.	UU	M. Sanni Ali, R.H.H. Groenwold, S.V. Belitser, P.C. Souverein, H. Gardarsdottir, A.W. Hoes, A. de Boer, Olaf H. Klungel	WP2 (WG2)
18 Propensity Score Matching and Unmeasured Covariate Imbalance: a simulation study.	UU	M. Sanni Ali, R.H.H. Groenwold, S.V. Belitser, A.W. Hoes, A. de Boer, O.H. Klungel	WP2 (WG2)
19 Negative control study on the risk of acute myocardial infarction associated with the use of antibiotics using a US database.	SANOFI	Tcherny-Lessenot S, Wang Y, Juhaeri J, Kurz X, Auclert L, Caubel P.	WP6
20 Impact of subgroup analyses and adjustment by stratification on safety signal detection for individual case reports".	MHRA	Seabroke S, Juhlin K, Candore G, Wisniewski A, Quarcoo N, Painter JL, Soeria-Atmadja D, Tregunno P, Norén GN, Slaterry J.	WP3
21 Structured assessment for prospective identification of potential safety signals in electronic health records.	NU	Cederholm S, Asimwe A, Bate A, Bhayat F, Brobert G, Hill G, Star K, Norén GN.	WP3
22 Evaluation of statistical measures for adverse drug interaction surveillance.	WHO-UMC	Juhlin K, Soeria-Atmadja D, Thakrar B, Norén GN.	WP3
23 Comparison of Signal Detection Methods.	EMA	Slaterry J., Candore G., Wisniewski A., Manlik K., Seabroke S., Juhlin K., Kayser M.	WP3 (WS1)

Title	Lead Author	Authors	WP
24 Seeking patient-reported information on medication use, without health care professional intervention: PROTECT Pilot Results.	Outcome	Dreyer N.A., Mt-Isa S., Richardson J.L., Laursen M., Zestra-van der Woude A.P., de Jong-van den Berg L.T.W., Jamry A., Thomas S.H.L., Blackburn S.C.F.	WP4
25 Internet advertisement methods provide highest levels of recruitment to a prospective non-interventional pilot study of self-reported medication use and pregnancy outcomes.	NEWCASTLE	Richardson J.L., Thomas S.H.L., Jamry A., de Jong-van den Berg L.T.W., Zestra-van der Woude A.P., Laursen M., Dreyer N.A., Mt-Isa S., and Blackburn S.C.F.	WP4
26 Comparison of ATRIA, CHADS2, and CHA2DS2-VASc risk stratification schemes for the prediction of stroke in the individual patient with atrial fibrillation and the impact on treatment decisions.	UU	Hendrika A. van den Ham, Olaf H. Klungel, Daniel Singer, Hubert. G.M. Leufkens, Tjeerd P. van Staa.	WP2