## European Directorate for the Quality of Medicines & HealthCare Council of Europe

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## Patient centred medication review – the 7 steps process

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Medication Reviews in Europe (EDQM) - 20<sup>th</sup> May 2025





### Who was delivering iSIMPATHY?

#### **Project Partners**

Scottish Government / NHS Scotland Northern Health & Social Care Trust / Medicines **Optimisation Innovation Centre in Northern Ireland** Health Service Executive in the Republic of Ireland

#### Funding

The project was funded by the EU Interreg and managed by the Special EU bodies programmes body (SEUPB). Total funding: €3,520,671 which includes 15% contribution from project partners.















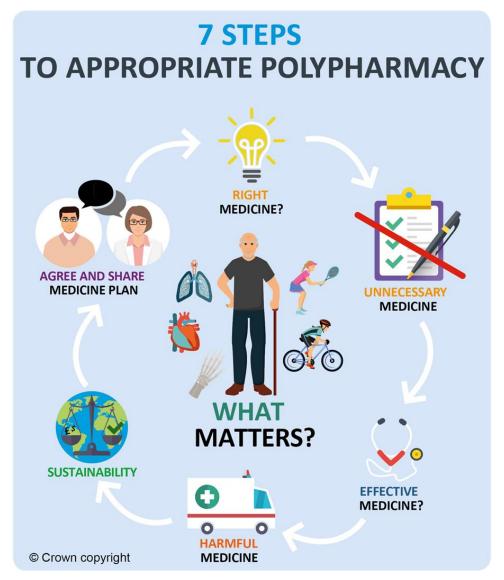






### **iSIMPATHY**

- £3.1m EU funded project
- Pharmacists recruited, trained, QA processes, practices/locations recruited
- Patients at high risk of medication-related harm:
  - Polypharmacy or
  - high risk meds or
  - care home or end of life
- Pharmacists delivered 7 steps reviews
- In-patients in NI, GP practices in ROI and multiple settings in Scotland
- Follow up with doctors, healthcare professionals and patient as required





### Important for patients:

- ★A medicines review is a meeting to talk about all of your medicines with an expert such as a pharmacist, doctor, or nurse.
- ★ As part of the **iSIMPATHY** project, medicines reviews are carried out by one of our specialist pharmacists. These pharmacists will work with your wider health care team to help you get the most from your medicines.

#### **\***Why do I need a medicines review?

- ★ The aim of a medicines review is to ensure that your medicines are helping you with What Matters to You in your life.
- ★When you are first prescribed a medicine, it is usually the best one for you; however, things change: You might have developed a side effect



# Important for healthcare professionals and healthcare system:

**iSIMPATHY** is important because medicine reviews achieve the best outcomes for patients' health and wellbeing.

★ Medicine reviews are also cost-effective: not only owing to immediate interventions such as medicine optimisation (which may result in deprescribing) but also because of the downstream effect reviews can have, such as reduced hospital admissions, time in hospital, and other primary care and social care settings.



### Who should I be reviewing?

Medicine reviews for adult patients will be prioritised according to the following categories:

- **Prescribed 10 or more medicines** (this will identify those from deprived communities where the average age is lower when taking 10 or more medications).
- **\* On high-risk medication** (as defined by the case finding indicators, regardless of the number of medications taken).
- Approaching the end of their lives: adults of any age, approaching the end of their life due to any cause, are likely to have different medication needs, and risk versus benefit discussions will often differ from healthy adults with longer expected life spans. Consider frailty score.
- ★Aged 50 years and over and resident in a care home, regardless of the number of medicines prescribed.



### 7 STEPS Medicine Review Tool

Domain	Step (7 steps)			
Aims	1. What matters to the patient?			
Need	2. Identify essential drug therapy.			
	3. Does the patient take unnecessary drug therapy?			
Effectiveness	4. Are therapeutic objectives being achieved?			
Safety	5. Does the patient have ADR/Side effects or are they at risk of ADRs/Side effects? Does the patient know what to do if they are too ill?			
Cost-Effectiveness	6. Is drug therapy cost-effective?			
Patient Centeredness	7. Is the patient willing and able to take drug therapy as intended?			





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### 7 STEPS Medicine Review Tool : Example (1/3)

Domain	Steps	Process			
Aims	1. What matters to the patient?	<ul> <li>Review diagnoses and identify therapeutic objectives with respect to:</li> <li>What matters to me (the patient)?</li> <li>Understanding of objectives of drug therapy</li> <li>Management of existing health problems</li> <li>Prevention of future health problems</li> </ul>			
Need	2. Identify essential drug therapy	<ul> <li>Identify essential drugs (not to be stopped without specialist advice):</li> <li>Drugs that have essential replacement functions (e.g., levothyroxine)</li> <li>Drugs to prevent rapid symptomatic decline (e.g., drugs for Parkinson's disease, heart failure)</li> </ul>			
	3. Does the patient take unnecessary drug therapy?	<ul> <li>Identify and review the (continued) need for drugs:</li> <li>With temporary indications</li> <li>With higher than usual maintenance doses</li> <li>With limited benefit in general for the indication they are used for</li> <li>With limited benefit in the patient under review (See: Drug Efficacy NNT table)</li> </ul>			
Effectiveness	4. Are therapeutic objectives being achieved?	<ul> <li>Identify the need for adding/intensifying drug therapy in order to achieve therapeutic objectives:</li> <li>To achieve symptom control</li> <li>To achieve biochemical/clinical targets</li> <li>To prevent disease progression/exacerbation</li> </ul>			

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### 7 STEPS Medicine Review Tool : Example (2/3)

Domain	Steps	Process
Safety	5. Does the patient have ADR/Side Effects or is at risk of ADRs/Side Effects? Does the patient know what to do if they're ill?	<ul> <li>Identify patient safety risks by checking for:</li> <li>Drug-disease interactions</li> <li>Drug-drug interactions (see Cumulative Toxicity tool)</li> <li>Robustness of monitoring mechanisms for high-risk drugs</li> <li>Risk of dose-dependent adverse effects due to drug-drug interactions</li> <li>Risk of accidental overdosing (Yellow Card Scheme)</li> <li>Identify adverse drug effects by checking for:</li> <li>Specific symptoms/laboratory markers (e.g., hypokalemia)</li> <li>Cumulative adverse drug effects (see Cumulative Toxicity tool)</li> <li>Drugs that may be used to treat ADRs caused by other drugs</li> <li>Sick Day Rule guidance can be used to help patients know what do with their medicines if they fall ill</li> </ul>
Cost- effectiveness	6. Is drug therapy cost- effective?	<ul> <li>Identify unnecessarily costly drug therapy by:</li> <li>Considering more cost-effective alternatives (but balance against effectiveness, safety, convenience)</li> </ul>





### 7 STEPS Medicine Review Tool : Example (3/3)

Domain	Steps	Process
Patient centeredness	7. Is the patient willing and able to take drug therapy as intended?	<ul> <li>Does the patient understand the outcomes of the review? Does the patient understand why they need to take their medication?</li> <li>Consider Teach back</li> <li>Ensure drug therapy changes are tailored to patient preferences</li> <li>Is the medication in a form the patient can take?</li> <li>Is the dosing schedule convenient?</li> <li>Consider what assistance the patient might have and when this is available</li> <li>Is the patient able to take medicines as intended?</li> <li>Agree and Communicate Plan</li> <li>Discuss with the patient/carer/welfare proxy therapeutic objectives and treatment priorities</li> <li>Decide with the patient/carer/welfare proxies what medicines have an effect of sufficient magnitude to consider continuation or discontinuation</li> <li>Inform relevant healthcare and social care carers of changes in treatments across care interfaces</li> <li>Add READ code 8B31B to the patient's record so that when they move across transitions of care it is clear their medication has been reviewed</li> </ul>





### Training

## Royal College of Physicians (RCP) accredited HCPs (TURAS)

https://learn.nes.nhs.scot/59670/isimp athy-evidence-based-polypharmacy



#### Modules

#### **ONE – Why should we address Polypharmacy**

- Definition and dangers of Polypharmacy
- Medication Adherence
- Adverse Drug reactions
- Criteria for selection for Polypharmacy reviews
- Short introduction to the '7 step' medication review process

#### TWO – 7 Steps Methodology

- The 7 Step Medication review process
- Numbers Needed to Treat
- The 7 steps review process in practice

### THREE – Change Methodology and Numbers Needed to Treat

- Implementing Change Methodology
- Case study example of the '7 steps in practice'
- 'Understanding NNT's' Numbers Needed to Treat





# Peer and project team support including Project ECHO sessions

Date	Curriculum/Education Topic				
27 May 2021	Numbers Needed to Treat for Hard Pressed Pharmacists				
24 June 2021	Skills & Tools to Manage Difficult Conversations				
23 September 2021	Pain Management in the Frail				
21 October 2021	A Day in the Life of the iSIMPATHY Pharmacist – 3 nations				
25 November 2021	High Risk Combinations in relation to anti-thrombotics				
16 December 2021	Tapering of Antidepressants – generically psychoactive agents				
27 January 2022	Parkinson's Disease & minimising the risk of falls				
24 February 2022	Maximising the Impact of the Consultation				

#### MOIC iSimpathy ECHO Network End of Year Survey

#### **Objective & Summary**

To provide peer support and shared learning environment for the appointed iSimpathy pharmacists. Through the project, training will be delivered to pharmacist and other medical professionals to undertake 15,000 structured polypharmacy reviews, which fits in to the overall clinical area of medicines optimisation.

	Objectives - Particpants review of s being met:
	63% Delivering education in specific areas of concern.
	88% Increasing confidence in delivery of reviews.
	63% Creating a community of support.
-	25% agreed expanding the iSimpathy Network has progressed 'a lot' or 'a great deal'.

50% agreed expanding the iSimpathy Network has progressed a 'moderate amount.'



86% of participants learned something through ECHO that ha been applied to their practice.

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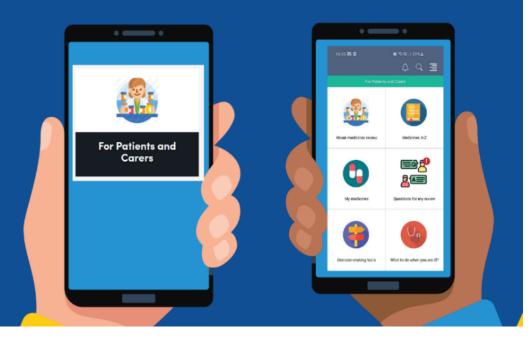


14 **24 March 2022** Issues Surrounding Diabetes / Cardio Metabolic issues

#### **Robust evaluation**

#### Supporting reviews with the Manage Medicines app

The <u>Manage Medicines app</u> is a key way to support the medicines reviews process. With easy to navigate toolkits for both professionals and patients or carers, the app also lets patients answer questions ahead of their reviews. As well as giving practitioners this information in advance, it helps patients get the most out of their medicines reviews. Look out for our short animation explaining the app and the PROMs (Patient Reported Outcomes Measures) questionnaire coming soon on our website and twitter.



#### *t* Interventions

• Eadon – type, result, clinical significance

#### **\***Appropriateness

- Person-centred modification of the medication appropriateness index implicit tool (PC-MAI)
- Polypharmacy indicators based on explicit tools (Polypharmacy Guidance)
- Patient reported outcome measures (PROMS)
- Economic analysis

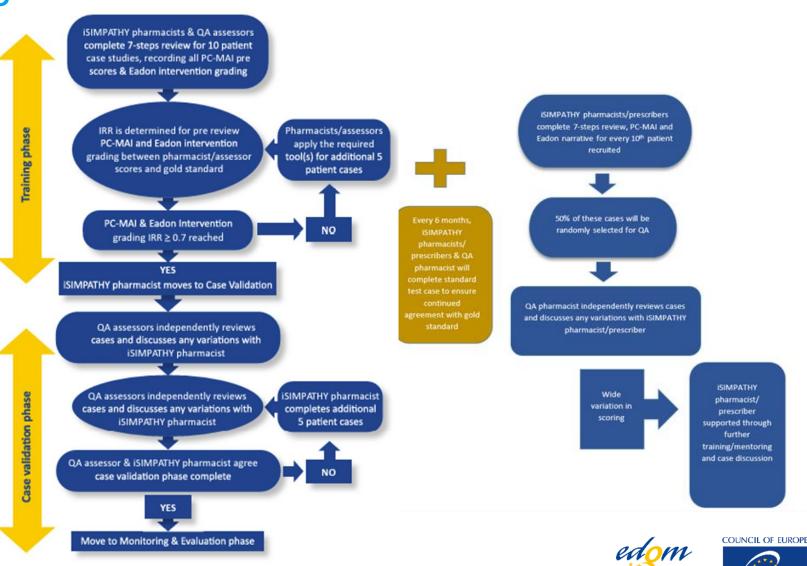


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### Quality assurance

- Training, guidance, peer review
- Eadon grading and PC-MAI scoring of standard cases
- **\***Interrater reliability
- Ongoing peer case reviews, quality assurance process





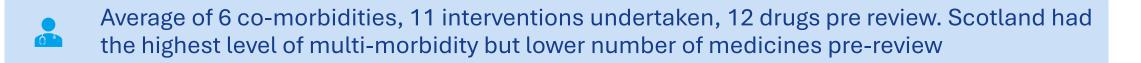


#### **Overview**

Reviews carried out in multiple settings: hospital, out-patient clinics and GP practices



Reviewed over 6000 people, average age 72, 53% female. Variation between countries: ROI and NI, people were older (75 and 72), in Scotland age was 67 with more males reviewed





95% of patients on 5 or more medicines, 35% on high-risk medicines



23% most deprived, 65% average, 12% least deprived





### Interventions

Eadon Result Category	Count
Prescription altered (stop)	3,904
Specific or additional patient/carer education	3,588
Requested/reviewed test/investigation/measurement e.g. labs, vital signs, spirometry	3,134
Medicines reconciled (iSIMPATHY intervention)	2,622
Standard patient and/or carer education (iSIMPATHY intervention)	2,622
Information given – healthcare professional	2,341
Prescription altered (start)	1,813
Referral made	1,427
Prescription altered (decrease)	1,345
Information given – patient	1,267
Other	1,205
Prescription endorsed e.g. medication record endorsement	1,134
Prescription unaltered advice accepted *	768
Prescription altered (increase)	563
Unresolved *	511
Prescription unaltered advice NOT accepted *	415
Patient's own medicines reviewed	102

**Total:** 28,761 Unaltered and unresolved account for 6% of total interventions indicating that 94% of interventions were actioned at the time of data collection.

Eadon Grading (n=2,623)	Total (%)
1. Detrimental to patient	0
2. No significance to patient	412 (1%)
3. Significant: does not improve patient care	3,878 (14%)
4. Significant: improves patient care	23,463 (82%)
5. Very significant; prevents a major organ failure or adverse reaction of similar importance	968 (3%)
6. Potentially lifesaving	
Total	28,721





### Change in appropriate polypharmacy – PC-MAI

• 92% of patients had a decrease in PC-MAI score, no patient had an increase

	Mean (SD)	ROI (n=228)	NI (n=54)	Scot (n=80)
Pre-review summated PC- MAI (n=376)	20.6 (15.0)	25.4 (15.2)	12.4 (9.5)	12.5 (11.3)
Post-review summated PC- MAI (n=367)	6.8 (8.8)	9.3 (9.8)	1.9 (3.2)	3.1 (4.6)
Difference	13.8	16.1	10.5	9.4

Pre-review PC-MAI in ROI twice that in Scotland and NI



#### Change in appropriate polypharmacy – polypharmacy indicators

- Increased likelihood of a • serious adverse outcome due to medication-related harm.
- Triggered 1,179 times in 793 patients, with risk fully resolved for 77% of the indicators

Indicator category	Number	%	Most common indicator	
Bleeding	324	27.5%	Patient on an oral anticoagulant is prescribed an antiplatelet n=116	
Falls	304	25.8%	Patient without dementia aged 75 years or older is prescribed TWO or more drugs with significant sedating or anticholinergic effects (excluding drugs only used for epilepsy) n=171	
Renal	149	12.6%	Patient with eGFR <60 and on an ACEI or ARB is prescribed an NSAID n=51	
Cardiac	123	10.4%	Patient is prescribed a betablocker and has a pulse of <60bpm n=63	
Hyperkalaemia	57	4.8%	Patient on an ACEI or ARB, potassium sparing diuretic, aliskiren or potassium supplement has hyperkalaemia (last K >5.5 mmol/l) n=23	
Hypoglycaemia	48	4.1%	Patient aged 65 or older without dementia is on intensive hypoglycaemic therapy and HbA1c is <48 (<6.5%) n=20	
Cerebrovascular disease	46	3.9%	Patient with AF and CHADSVASC score >=3 is not prescribed an oral anticoagulant n=34	





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#### **iSIMPATHY:** Impact of comprehensive person-centred medicines reviews



iSIMPATHY embedded a multidisciplinary collaborative approach to deliver pharmacist-led, person-centred medicines reviews using the 7-Steps methodology.

8.6 million unplanned hospital admissions each year across Europe due to adverse drug reactions



50% of hospital admissions due to adverse drug reactions are preventable

#### **Over 6400** patients reviewed

 average age 72 53% female

average 6

co-morbidities



Average 11 interventions per review e.g. education, medicine reconciliation, drug changes, monitoring

iSIMPATHY's methodology can be applied across healthcare systems. An implementation pack and accredited online training is available.

"We have definitely made significant changes to medications as a direct result of these reviews and advice." (Consultant, Scotland)

Direct medicines cost savings per review of £131 and potential total of £1688 savings from avoided healthcare resource usage

82% of interventions rated clinically significant. 4% of interventions (968) potentially prevented major organ failure or adverse drug reactions of similar clinical importance

Medication Review: 7-Steps to Appropriate Polypharmacy



Appropriateness of medicine was improved in 92% of reviews



Average reduction of 1 medicine: 12 to 11

Better understanding of medicines, improved adherence and less harm reported in Patient Reported Outcome Measures (PROMs) and average 7.4 Quality-Adjusted Life Years (QALY) gained per 100 patients.

"Before my medication review, I suffered badly with heavy legs and wheezing... after just a few small changes to my tablets I'm now out walking for 30 minutes every morning." (Patient, Ireland)





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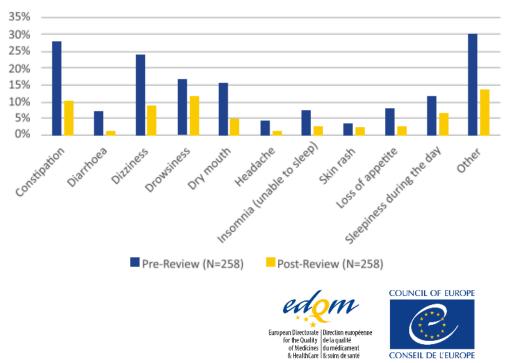
### Patient experience – Patient Reported Outcome Measures (n=258)

PROMS with difference between pre- and post-review responses (p<0.05)

	Pre- review	Post- review
Understanding of purpose of medicines	16%	93%
Understanding of problems medicines may cause	13%	93%
Experiencing side effects	64%	34%
Ever have problems remembering to take medicines?	14%	1%
Stopped taking medicine(s) when felt better?	14%	1%
Stopped taking medicine(s) when felt worse?	22%	3%
I have no problem performing my usual activities	58%	69%
I have no pain or discomfort	48%	56%
I am not anxious or depressed	63%	73%

"huge improvement – walked for half an hour this morning, used to have to stop every few minutes because of the dizziness" Patient

Patient self-reported side effects categories



### What patients say...



'The service and empathy I received from the hospital chemist was very comforting. She was able to help me understand how the medication I would need would benefit my health. At the moment my health has improved and the medication I have been given has served their purpose well. Thank you for your help.' 'No one has ever sat down with me and taken time to go through all my medicines with me'

'It means so much to me to be involved in decisions about my brother's care. He is non-verbal and I do everything for him'

'The pharmacist I spoke to was so friendly and helpful reassuring me with regard to my medication. My health has certainly improved as I understood more about any medicines I was taking. She explained what the tablets were for and why each dosage was being given. I would highly recommend this service to anyone' 'A wonderful person. It was the first time anyone ever listened and understood what I was coping with and helped me in so many ways. I wish you all the very best in your job'



### Pharmacist experience (qualitative interviews)

- Pharmacists felt the impact on patients was substantial, with improved quality of care and patient understanding and autonomy.
- The 7 steps model and the project approach (including time available) contributed to the effects.
- Project training, guidance and experience gained during the project impacted on professional practice directly and practice of colleagues was positively impacted also.

My clinical knowledge is completely...it's completely changed. It's very vast, I see things from a completely different perspective from when I started iSIMPATHY There's a lot more honesty coming from the patients as well. They feel like they've got time to talk... Tell you what their anxieties are around medications...

...they're able to do more things or able to get out a bit more or even kind of more confident





# Multidisciplinary team experience (survey)

- Enablers: Good communication, funding, support from and engagement with the project
- Barriers: Lack of funding, time to conduct review-related activity, work culture and the need to embrace change

#### Other team members' job satisfaction Your job satisfaction? Patient quality of life? Patient satisfaction with their care Patient understanding of their medicines Medication safety Prevention of hospital admission/attendence Medicine adherence Quality of medication reviews 0% 20% 100% Very positive effect Somewhat positive effect Neutral/No effect I don't know Somewhat negative effect Very negative effect

Effect of iSIMPATHY





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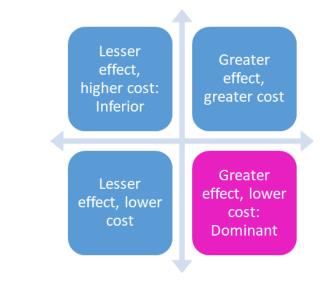
### Health economic analysis

Dominant in the health economic sense, delivering cost savings and QALY gains

#### ★ Per 100 reviews:

- ★ Cost £7,500 to deliver
- ★ Medication cost savings of £13,100
- ★ Avoided ADR-related hospital admissions £6,600
- ★ Avoided medical costs associated with interventions £168,800
- ★ 7.4 QALY gain
- Medication-related cost savings outweigh the cost of service delivery in ROI and Scotland

Reducing unplanned admissions from medicationrelated harm could save; **£24.7m** for ROI, **£11m** for NI and **£36m** for Scotland (avoidance of unplanned hospital admissions costs for 65yr+ in Scotland and ROI, 75yr+ age group in NI)



> Int J Clin Pharm. 2024 Aug;46(4):957-965. doi: 10.1007/s11096-024-01732-y. Epub 2024 May 30.

Economic cost-benefit analysis of person-centred medicines reviews by general practice pharmacists

Cian O'Mahony <sup>1</sup>, Kieran Dalton <sup>2</sup>, Leon O'Hagan <sup>3</sup>, Kevin D Murphy <sup>1</sup>, Clare Kinahan <sup>3</sup>, Emma Coyle <sup>3</sup>, Laura J Sahm <sup>1</sup>, Stephen Byrne <sup>1</sup>, Ciara Kirke <sup>4</sup>



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### Effect of scaling up

★If comprehensive medicine reviews were provided to all patients aged 65+ taking 5+ medicines in each country (75+ in NI) the maximum avoidable inpatient cost would be:

- ★ £24.7m for ROI
- ★ £11.0m for NI and:
- ★ £36.0m for Scotland

Methodology is scalable – iSIMPATHY has demonstrated that it can be of benefit across all healthcare settings.

- \* Implementation pack and accredited on-line training pack is available
- \* Over 200 healthcare professionals have already completed training





### Key contributors to success?

Adding dedicated capacity - time EZA



Person-centred – improved understanding facilitating shared decision making, minimised ? burden associated with participation (e.g. multiple questionnaires)

Access to information – medication and medical history, the patient, labs



Part of multidisciplinary team – patient and MDT trust





### www.iSIMPATHY.eu

#### Scale and spread

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### What now 1?

Available now (<u>www.isimpathy.eu</u>)
 Project resources, app, reports
 Online training via Turas

#### ★Scotland

★ Polypharmacy guidance update : 4<sup>th</sup> edition
 ★ Medicines review with Pharmacogenomics

#### **\***Northern Ireland

\*Adopting polypharmacy guidance and 7 steps methodology as standard

#### **\***Republic of Ireland

\*Engagement to convert evidence to business cases to roles







### What now 2?

★Innovation in person centred Medication Prescribing and Review for Optimal Value and Efficacy (€10 million)

\*10,000 reviews including pharmacogenomics and/or 7 step structured medication review

**★** Derry GP Federation, Donegal and Sligo and Tayside in Scotland

**★**Four-year project from March 2025 - March 2029









#### **isimpathy Evaluation Report**



ISIMPATHY is supported by the European Union's INTERREG VA Northern Ireland - Ireland - Scotland Programme and managed by the Special EU Programmes Body (SEUPB)







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