Latest Guidance on Pharmacological Management of Type 2 Diabetes
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Managing Director
Soar Beyond
About Soar Beyond

- Established in 2006 - working in and with the NHS
- Predominantly pharmacist-led
- Providers of clinical pharmacist services
- Passion, expertise and heritage in:
  - clinical pharmacist service provision
  - change management
  - training and performance management
  - web platform creation and content management
  - large-scale deployment
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|                      | • Web platform
|                      | • Supported by training workshops |

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|                      | • Training workshops
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Objectives

• To provide an overview of guidance on the pharmacological management of type 2 diabetes mellitus*
• To highlight key similarities and differences in recommendations between the guidelines
• To provide practical points for implementation in primary care

Session Outline

• Outline the guidance for the pharmacological management of type 2 diabetes mellitus using the Guidelines summary table comparing recommendations from SIGN guideline 154, NICE Guideline 28, and the ADA/EASD consensus report highlighting:
  o overlap between the guidelines
  o any conflicting points from the guidelines

• Provide practical advice on how the practice-based pharmacist can support patient management through implementing the guidance to:
  o improve clinical outcomes
  o reduce GP workload
Michelle Lam
Diabetes Specialist Pharmacist
NHS Luton CCG
My Experience / Background

• Hospital pharmacist by background, CCG and primary care experience
• Honorary Clinical Lecturer at University of Manchester
• UKCPA Diabetes & Endocrinology Committee Member
• Lecturer at Bradford School of Pharmacy
• Diabetes-related publications
Conflicts of Interest / Declarations

• Consultancy for Novo Nordisk
NICE NG28 - algorithm for blood glucose lowering therapy in adults with type 2 diabetes

**Algorithm for Blood Glucose Lowering Therapy in Adults with Type 2 Diabetes**

1. **If Hba1c rises to 58 mmol/mol (7.5%) on lifestyle interventions:**
   - **First consultation:**
     - Consider dual therapy with a biguanide and either a GLP-1 receptor agonist or a SGLT2 inhibitor.
     - **Continued therapy:**
       - If Hba1c remains over 53 mmol/mol (7.0%), consider insulin or metformin in combination.

2. **If Hba1c rises to 68 mmol/mol (8.0%) on lifestyle interventions:**
   - **First consultation:**
     - If lifestyle measures alone are not effective, consider dual therapy with a biguanide and either a GLP-1 receptor agonist or a SGLT2 inhibitor.
     - **Continued therapy:**
       - If Hba1c remains over 53 mmol/mol (7.0%), consider Basal insulin.

**Insulin-based treatment**
- Consider sitagliptin in combination with insulin.
- Consider dual therapy with a GLP-1 receptor agonist and an SU.

**Insulin-based treatment**
- Consider dual therapy with a GLP-1 receptor agonist and an SU.

**References**
- NG28 (issued December 2015): Type 2 diabetes in adults: management.
**Scottish Intercollegiate Guidelines Network (SIGN)**

Pharmacological management of glycaemic control in people with T2D

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**Two key recommendations:**

1. **2.3: SODIUM GLUCOSE CO-TRANSPORTER 2 INHIBITORS**
   
   In individuals with type 2 diabetes and established cardiovascular disease, SGLT-2 inhibitors with proven cardiovascular benefit (currently empagliflozin and canagliflozin) should be considered.

2. **2.4: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS**
   
   For individuals with type 2 diabetes and established cardiovascular disease, GLP-1 receptor agonist therapies with proven cardiovascular benefit (currently liraglutide) should be considered.

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**Adapted from** http://www.sign.ac.uk [accessed December 2017]. Additional footnotes are available in the notes of this slide.
ADA-recommendations\(^{(18)}\)

At diagnosis, initiate lifestyle management, set A1C target, and initiate pharmacologic therapy based on A1C:

- **A1C is less than 9%, consider Monotherapy.**
- **A1C is greater than or equal to 9%, consider Dual Therapy.**
- **A1C is greater than or equal to 10%, blood glucose is greater than or equal to 300 mg/dL, or patient is markedly symptomatic, consider Combination Injectable Therapy** (See Figure 3).

300mg/dL = 16.6mmol/L

Glucose-lowering Medication in Type 2 Diabetes

**FIRST-LINE THERAPY IS METFORMIN AND COMPREHENSIVE LIFESTYLE**
*INCLUDING WEIGHT MANAGEMENT AND PHYSICAL ACTIVITY*
*IF HbA1c ABOVE TARGET PROCEED AS BELOW*

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**Established ASCVD or CKD**

**ASCVD predominates**

**HF OR CKD predominates**

---

**Metformin**, on top of lifestyle intervention, remains as the recommended first line glucose-lowering medication for patients with type 2 diabetes

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1. Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1RA strongest evidence for liraglutide > semaglutide > exenatide extended release. For SGLT-2i evidence modestly stronger for empagliflozin > canagliflozin.
2. Be aware that SGLT-2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use.
3. Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs.
4. Degludec or U100 glargine have demonstrated CVD safety.
5. Low dose may be better tolerated though less well studied for CVD effects.
6. Choose later generation SU with lower risk of hypoglycaemia.
7. Degludec / glargine U300<glargine U100 / detemir<NDH insulin.
8. Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide.
9. If no specific comorbidities (i.e. no established CVD, low risk of hypoglycaemia and lower priority to avoid weight gain or no weight-related comorbidities).
10. Consider country- and region-specific cost of drugs. In some countries, TZDs relatively more expensive and DPP-4i relatively cheaper.

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FIRST-LINE THERAPY IS METFORMIN AND COMPREHENSIVE LIFESTYLE
(INCLUDING WEIGHT MANAGEMENT AND PHYSICAL ACTIVITY)
IF HbA1c ABOVE TARGET PROCEED AS BELOW

Established ASCVD or CKD

ASCVD predominates

If HbA1c above target

Either/or

- GLP-1RA with proven CVD benefit\(^1\)
- SGLT-2i with proven CVD benefit\(^1\) if eGFR adequate\(^2\)

If further intensification is required or patient is now unable to tolerate GLP-1RA and/or SGLT-2i, choose agents demonstrating CV safety:
- Consider adding the other class (GLP-1RA and/or SGLT-2i) with proven CVD benefit
- DPP-4i if not on GLP-1RA
- Basal insulin\(^4\)
- TZD\(^5\)
- SU\(^6\)

HF OR CKD predominates

If HbA1c above target

PREFERABLY

- SGLT-2i with evidence of reducing HF and/or CKD progression in CVOT if eGFR adequate\(^2\)

OR

- If SGLT-2i not tolerated or contraindicated or if eGFR less than adequate\(^2\), add GLP-1RA with proven CV benefit\(^3\)

Avoid TZD in the setting of HF

Choose agents demonstrating CV safety:
- Consider adding the other class with proven CVD benefit\(^1\)
- DPP-4i (not saxagliptin) in the setting of HF (if not on GLP-1RA)
- Basal insulin\(^4\)
- SU\(^6\)

\(^1\)Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1RA strongest evidence for liraglutide>semaglutide>exenatide ER. For SGLT-2i evidence modestly stronger for empagliflozin>canagliflozin.

\(^2\)Be aware that SGLT-2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use.

\(^3\)Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs.

\(^4\)Degludec or U100 glargine have demonstrated CVD safety.

\(^5\)Low dose may be better tolerated though less well studied for CVD effects.

\(^6\)Choose later generation SU with lower risk of hypoglycaemia.

To avoid clinical inertia reassess and modify treatment regularly (3–6 months)

Without established ASCVD or CKD

Compelling need to minimise weight gain or promote weight loss

Cost is a major issue\(^9,10\)

To HbA1c above target

If HbA1c above target

- Avoid TZD in the setting of HF

Choose agents demonstrating CV safety:
- Consider adding the other class with proven CVD benefit\(^1\)
- DPP-4i (not saxagliptin) in the setting of HF (if not on GLP-1RA)
- Basal insulin\(^4\)
- SU\(^6\)

\(^9\)Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1RA strongest evidence for liraglutide>semaglutide>exenatide ER. For SGLT-2i evidence modestly stronger for empagliflozin>canagliflozin.

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Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs.

Degludec or U100 glargine have demonstrated CVD safety.

Low dose may be better tolerated though less well studied for CVD effects.

Choose later generation SU with lower risk of hypoglycaemia.

Glucose-lowering Medication in Type 2 Diabetes

FIRST-LINE THERAPY IS METFORMIN AND COMPREHENSIVE LIFESTYLE
(INCLUDING WEIGHT MANAGEMENT AND PHYSICAL ACTIVITY)
IF HbA\textsubscript{1c} ABOVE TARGET PROCEED AS BELOW

Without established ASCVD or CKD

If HbA\textsubscript{1c} above target
- DPP-4i
  - SGLT-2i\textsuperscript{2}
    - GLP-1RA
      - TZD
      - OR
        - SGLT-2i\textsuperscript{2}
          - GLP-1RA
            - OR
              - DPP-4i
                - TZD
                - OR
                  - GLP-1RA

Continue with addition of other agents as outlined above

If HbA\textsubscript{1c} above target
- Consider the addition of SU\textsuperscript{6} OR basal insulin:
  - Choose later generation SU with lower risk of hypoglycaemia
  - Consider basal insulin with lower risk of hypoglycaemia\textsuperscript{7}

To avoid clinical inertia reassess and modify treatment regularly (3–6 months)

Established ASCVD or CKD, HF OR CKD predominates

Without established ASCVD or CKD

If HbA\textsubscript{1c} above target
- Consider the addition of SU\textsuperscript{6} OR basal insulin:
  - Choose later generation SU with lower risk of hypoglycaemia
  - Consider basal insulin with lower risk of hypoglycaemia\textsuperscript{7}

Compelling need to minimise hypoglycaemia

Cost is a major issue\textsuperscript{9,10}


\textsuperscript{2}Be aware that SGLT-2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use

\textsuperscript{6}Choose later generation SU with lower risk of hypoglycaemia

\textsuperscript{7}Degludec / glargine U300<glargine U100 / detemir<NPH insulin

\textsuperscript{9}Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1RA strongest evidence for liraglutide>semaglutide>exenatide extended release. For SGLT-2i evidence modestly stronger for empagliflozin>canagliflozin; Be aware that SGLT-2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use;

\textsuperscript{10}Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs; Degludec or U100 glargine have demonstrated CVD safety; Low dose may be better tolerated though less well studied for CVD effects; Choose later generation SU with lower risk of hypoglycaemia; Degludec / glargine U300<glargine U100 / detemir<NPH insulin;

\textsuperscript{2}Semaglutide-liraglutide-dulaglutide-exenatide-exenatide; If no specific comorbidities (i.e. no established CVD, low risk of hypoglycaemia and lower priority to avoid weight gain or no weight-related comorbidities);

\textsuperscript{5}Consider country- and region-specific cost of drugs. In some countries, TZDs relatively more expensive and DPP-4i relatively cheaper

Glucose-lowering Medication in Type 2 Diabetes

**FIRST-LINE THERAPY IS METFORMIN AND COMPREHENSIVE LIFESTYLE**
**INCLUDING WEIGHT MANAGEMENT AND PHYSICAL ACTIVITY**
IF HbA$_1c$ ABOVE TARGET PROCEED AS BELOW

1. Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1RA strongest evidence for liraglutide > semaglutide > exenatide extended release. For SGLT-2i evidence modestly stronger for empagliflozin > canagliflozin; 
2. Be aware that SGLT-2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use; 
3. Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs; 
4. Degludec or U100 glargine have demonstrated CVD safety; 
5. Low dose may be better tolerated though less well studied for CVD effects; 
6. Choose later generation SU with lower risk of hypoglycaemia; 
7. Degludec / glargine U300<glargine U100 / detemir-NPH insulin; 
8. Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide; 
9. If no specific comorbidities (i.e. no established CVD, low risk of hypoglycaemia and lower priority to avoid weight gain or no weight-related comorbidities); 
10. Consider country- and region-specific cost of drugs. In some countries, TZDs relatively more expensive and DPP-4i relatively cheaper

Glucose-lowering Medication in Type 2 Diabetes (19, 20)

**FIRST-LINE THERAPY IS METFORMIN AND COMPREHENSIVE LIFESTYLE**
INCLUDING WEIGHT MANAGEMENT AND PHYSICAL ACTIVITY
**IF HbA₁c ABOVE TARGET PROCEED AS BELOW**

1. **Established ASCVD or CKD**
   - **ASCVD predominates**
   - **HF OR CKD predominates**

2. **Without established ASCVD or CKD**
   - **Compelling need to minimise hypoglycaemia**
   - **Compelling need to promote weight loss or avoid weight gain**

3. **Cost is a major issue**

4. **Choose later generation SU with lower risk of hypoglycaemia**

5. **If no specific comorbidities (i.e. no established CVD, low risk of hypoglycaemia and lower priority to avoid weight gain or no weight-related comorbidities)**

6. **Consider country- and region-specific cost of drugs. In some countries, TZDs relatively more expensive and DPP-4i relatively cheaper**

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Glucose-lowering Medication in Type 2 Diabetes

First-line therapy is metformin and comprehensive lifestyle (including weight management and physical activity). If HbA1c above target proceed as below.

**Without established ASCVD or CKD**

- Compelling need to minimise hypoglycaemia
  - GLP-1RA
  - SGLT-2i
  - DPP-4i
  - TZD

- Compelling need to minimise weight gain or promote weight loss
  - GLP-1RA with good efficacy for weight loss
  - SGLT-2i

**Established ASCVD or CKD**

- HF OR CKD predominates
  - Preferably
    - SGLT-2i with evidence of reducing HF and/or CKD progression in CVOT if eGFR adequate
    - OR
    - GLP-1RA
    - TZD
  - If further intensification is required or patient is now unable to tolerate GLP-1RA and/or SGLT-2i, choose agents demonstrating CV safety:
    - Avoid TZD in the setting of HF
    - Consider adding the other class (GLP-1RA and/or SGLT-2i) with proven CVD benefit
    - DPP-4i if not on GLP-1RA
    - Basal insulin
    - TZD
    - SU

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NICE recommendations:

- When starting insulin, use a structured programme and continue metformin for people without contraindications or intolerance. Review the continued need for other blood glucose lowering therapies.
- Offer NPH insulin once or twice daily according to need.
- Consider starting both NPH and short-acting insulin either separately or as pre-mixed (biphasic) human insulin (particularly if HbA1c is 75 mmol/mol (9.0%) or higher).
- Consider using insulin detemir or glargine if the person: needs assistance to inject insulin, lifestyle is restricted by recurrent symptomatic hypoglycaemic episodes or would otherwise need twice-daily NPH insulin in combination with oral blood glucose lowering drugs.
- Consider analogue pre-mixed (biphasic) preparations if: the person prefers injecting insulin immediately before a meal, hypoglycaemia is a problem or blood glucose levels rise markedly after meals.
- Only offer a GLP-1 mimetic in combination with insulin with specialist care advice and ongoing support from a consultant-led multidisciplinary team.
- An SGLT-2i in combination with insulin with or without other antidiabetic drugs is an option.
- Monitor people on insulin for the need to change the regimen.

22. Type 2 diabetes in adults: management’, NICE guideline NG28. Published December 2015, last updated April 2017
ADA Injectable Therapy Guide


If A1C not controlled, consider combination injectable therapy

Add 1 rapid-acting insulin injection before largest meal

Start: 4 units, 0.1 U/kg, or 10% basal dose. If A1C <8%, consider basal by same amount
Adjust: ↑ dose by 1-2 units or 10-15% once or twice weekly until SMBG target reached
For hypo: Determine and address cause; if no clear reason for hypo, corresponding dose by 2-4 units or 10-20%

If A1C not controlled, advance to basal-bolus

Add ≥2 rapid-acting insulin injections before meals (‘basal-bolus’)

Start: 4 units, 0.1 U/kg, or 10% basal dose/meal. If A1C <8%, consider basal by same amount
Adjust: ↑ dose(s) by 1-2 units or 10-15% once or twice weekly to achieve SMBG target
For hypo: Determine and address cause; if no clear reason for hypo, corresponding dose by 2-4 units or 10-20%

Add GLP-1 RA

If not tolerated or A1C target not reached, change to 2 injection insulin regimen

If goals not met, consider changing to alternative insulin regimen

Change to premixed insulin twice daily (before breakfast and supper)

Start: Divide current basal dose into ⅔ AM, ⅓ PM or ½ AM, ½ PM
Adjust: ↑ dose by 1-2 units or 10-15% once or twice weekly until SMBG target reached
For hypo: Determine and address cause; if no clear reason for hypo, corresponding dose by 2-4 units or 10-20%

If A1C not controlled, advance to 3rd injection

Change to premixed analog insulin 3 times daily (breakfast, lunch, supper)

Start: Add additional injection before lunch
Adjust: ↑ doses by 1-2 units or 10-15% once or twice weekly to achieve SMBG target
For hypo: Determine and address cause; if no clear reason for hypo, corresponding dose by 2-4 units or 10-20%
### Similarities / Differences in Guidance

<table>
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<th>NICE NG 28</th>
<th>SIGN 154</th>
<th>ADA/EASD 2019</th>
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| • To date, the NICE NG28 guideline has not been updated to incorporate specific guidance from these CVOTs | • Taken account of evidence from CVOTs by distinguishing drug classes with CVD benefits  
• Recommendations on considering the use of SGLT2i and GLP1RA for those with established CVD | • Incorporated detailed guidance from CVOTs and recommendations categorised based on patient characteristics  
• CVD-focused drug intensification approach |
Key Recommendations

• Start with *metformin* if not contraindicated (monitor renal function)
• For patients who are at high CVD risk or overweight, choose an *SGLT2i or GLP-1RA* if not contraindicated
• Avoid *pioglitazone and saxagliptin* in heart failure
• *DPP4i* is for small goals, safe in frail elderly, stop when starting GLP-1RA
Type 2 Diabetes Case Study

- Mrs TY, 56 years old, South Asian ethnicity
- Weight 82kg, BMI 34, HbA1c 79, QRISK2 16.3%, eGFR>60, LFTs normal
- Microalbuminuria, hypertension, depression, osteoporosis, mild frailty
- Typical south-asian diet, physically inactive, non-symptomatic, no hypos
- Medication:
  - Glucophage 1g bd
  - Gliclazide 160mg bd
  - Linagliptin 5mg od
  - Atorvastatin 20mg od
  - Ramipril 10mg od
  - Amlodipine 10mg od
  - Sertraline 50mg od
  - Adcal-D3 T bd

What is the HbA1c target for this lady? What did I do?
Unmet Need – how can we improve the patient journey and management in primary care

• Patients’ diabetes knowledge and self-management skills are often poor
• Patient empowerment and activation is equally important to drug treatment
• Care continuity improves patient satisfaction
  o Consistent messages from HCPs
  o Service continuity
How can Pharmacists Help?

• Improve three treatment targets (HbA1c, BP, cholesterol) through:
  o patient motivation and education
  o identify and resolve medicines adherence issues
  o drug intensification, individualised therapy
• Complete nine care processes (QOF)
• Up-skilling of other primary care staff
Shailen Rao
Managing Director, Soar Beyond
Objectives

• Share how practice pharmacists can help optimise type 2 diabetes management in their practice / PCN
• Share a structured methodology (i2i ABCDE) for implementation
The Practice Pharmacist Journey

2016
- Wave 1 NHSE Pilot
- Aim: 2,000 GPPs by 2020
- Tapered funding
- Model at 1:15k patients
- Relatively new role

2017-2018
- Pilot extended
- Workload reduction achieved and effectiveness proven
- Challenges at new model at 1:30k
- Low uptake by practices
- Recruitment and retention challenges

2019
- NHS Long Term Plan launched
- PCNs established
- 70% recurrent funding for all PCNs
- GP pharmacists and PCNs deciding on retaining existing NHSE or absorbing into PCN

2024
- 5 pharmacists: 30-50k patients
- Aim: 5,000+ GP pharmacists – every practice to have access
- Gain share delivering shared savings
Different Focus in Roles

**Practice Pharmacist**
- Medication reviews
- Polypharmacy reviews
- Care home reviews
- **LTC management**
- Repeat prescribing
- HRD monitoring
- Integrated role working alongside MDT
- Clinical admin
  - DOCMAN
  - Med reviews
- QOF and income generation

**PCN Pharmacist**
- Develop the clinical skills and expertise to deliver the DES from 2020 onwards
- Process review and standardisation to create efficiency
- **Risk stratifying patients to manage practice workload**
- Working with the clinical director to establish pathways
- Integrating with wider healthcare team outside of PCNs
- Prescribing lead – gain share in future on prescribing costs

This is what many want however delivering this across 30,000 plus population is a challenge
ABCDE

Review Process

A
Agree Scope

B
Buy-in

C
Conduct Preparation

D
Deliver Clinic

E
Evaluate & Follow-up
Being Clear about the Scope of Practice

Complex patients
Triple therapy
Dual therapy
Diet and/or other monotherapy
Diet and/or metformin
Pre-diabetes/screening unknown population

Specialist supervision (Out of scope)

Smoking
BMI
Waist circumference
BP
HbA1c
Lifestyle
Cholesterol

Disease - increased risk of complications

Developed by the i2i Network Diabetes Faculty © Soar Beyond
Circle of Competence

- Input from GPs
- Indemnity & Safety
- Training
- Time

OUT OF SCOPE
STRETCHED
IN SCOPE
Practice Pharmacist Competencies – Type 2 Diabetes

1. How to identify a cohort of patients to safely and competently review

2. How to set safe individualised HbA1c targets and interpret HbA1c

3. Optimising treatment beyond metformin and individualising choices based on evidence and patient factors

4. Knowing comorbidities and how to reduce cardiovascular risk factors

5. Knowing how to individualise diet and lifestyle advice and goal setting/care planning

6. Understanding and applying sick day rules

7. Understanding when blood glucose monitoring is required and awareness of DVLA regulations with regards to blood glucose monitoring

8. Understanding how to identify and treat hypoglycaemia

9. How to showcase and evaluate your interventions and outcomes
Diabetes Pharmacist Framework

• Key tool to planning pharmacist specialist portfolio
• Fits within the FPF and APF to help demonstrate competencies in both professional frameworks
• No ‘award’ but gives structure to pharmacist development

Summary

- There is an unmet need and benefit in managing patients with type 2 diabetes more proactively
- The science and logic adds up... but who is going to do the work?
- PCNs and clinical pharmacists are potential enablers
- To get the best outcomes most efficiently, an organised and focussed solution is required
Thank you
Visit us on stand 58

https://soarbeyond.co.uk/

shailen@soarbeyond.co.uk