

# ABCD audits update

Dr Bob Ryder

ABCD Spring Meeting, Glasgow

May 24, 2018

“Remember when you were young, you  
shone like the sun”

Shine on you crazy diamond, Pink Floyd, 1975

“Now there's a look in your eyes, like black  
holes in the sky”

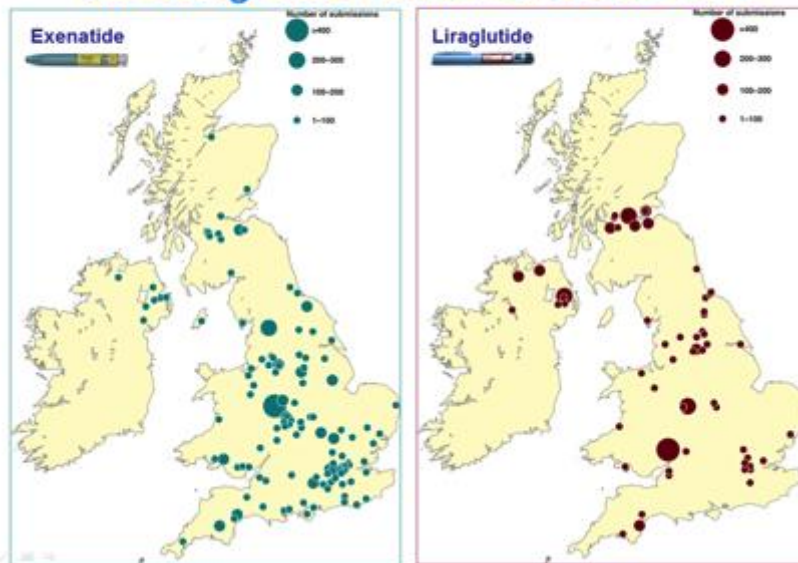
Shine on you crazy diamond, Pink Floyd, 1975

“Shine on you crazy diamond!”

Shine on you crazy diamond, Pink Floyd, 1975

# ABCD nationwide exenatide and liraglutide audits

Nationwide contribution to exenatide and liraglutide national audit 2011



- Real-life data
  - >13000 patients from
  - >150 centres
  - >500 contributors
- There had been (by 2018)
  - 12 published papers
  - 24 abstracts
  - 13 oral presentations

## ABCD nationwide exenatide audit contributors

The following are those whom we know about.

**ABCD nationwide exenatide audit project steering group:** Ryder REJ, Walton C, Rowles S, Adamson K, Dove D, Thozhukat S

**ABCD nationwide exenatide audit – initial setup, maintenance and nationwide analysis:** Ryder REJ, Walton C, Winocour P, Cull ML, Jose B, Sukumar N, Mills AP, Sands K, Shafiq W, Rigby A, Thozhukat S, Thong K. Statistician: Blann A.

**Addenbrookes Hospital:** Adler A, Evans M, Simmons D, O’Rahilly S, Coll T, Farooqi S, Park A. **Altnagelvin Area Hospital:** Lindsay J, Kelly J. **Antrim Area Hospital:** Kennedy A, Rooney D. **Barnsley Hospital:** Uchegbu E. **Basildon University Hospital:** Mulcahy M, Krishnan L. **Basingstoke and North Hampshire NHS Foundation Trust:** Guy R, Turner B, Akester K, Lewis G, Harrison O, Tombling S, Lloyd G, Hughes C, Lowe C. **Bedford Hospital:** Morrish N, Melvin A, Pledger J, Barron R. **Bedfordshire & Hertfordshire PGMS, Luton:** Rehman T, Sinclair A. **Belfast City Hospital:** Henry W. **Bolton Diabetes Centre:** Palin S, Kenz R. **Bristol Royal Infirmary:** Raghavan R, Phillips S, Bradley K. **Bronglais Hospital:** Kotonya C, Premawardhana LDKE. **Chesterfield Royal Hospital:** Mohammad M, Robinson RTCE, MacInerney RM. **Chorley & South Ribble Hospital:** Rajbhandari SM, Acharya S. **City Hospital, Birmingham:** Ryder REJ, Basu A, De P, Lee BC, Jose B, Sukumar N, McAloon CJ, 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## Acknowledgment

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ABCD nationwide liraglutide audit – initial setup, maintenance and nationwide analysis: Ryder REJ, Walton C, Thong KY, Sen Gupta P, Cull ML, Mills AP. Statistician: Blann A.

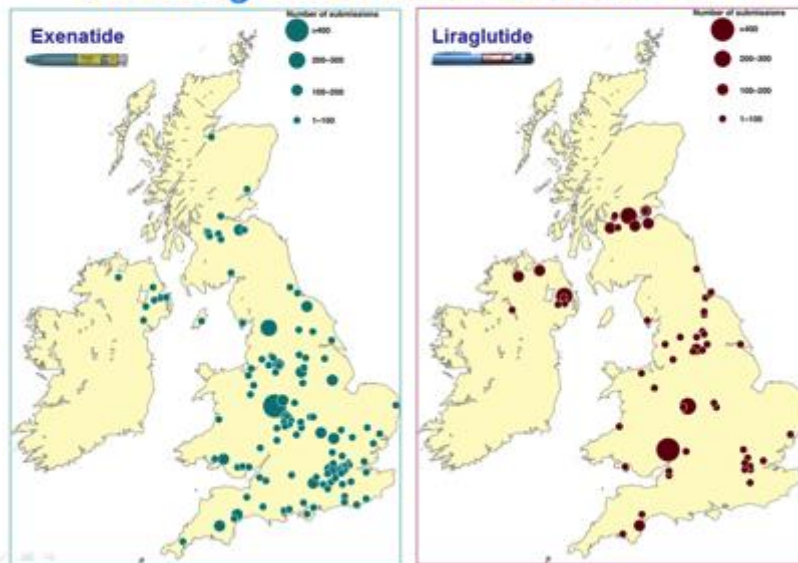
**Addenbrookes Hospital:** Adler A, Bejinariu E, Myring J, Park A, Parker V, Sarker A, Simmons D. **Altnagelvin Area Hospital:** Black R N, Caskey H, Cooke B, Early R, Giff K, Hamilton L, Helmy A F, King L, Lindsay J R, McCarroll F, McDaid A-M, McLivor E, Moles K W, Morahan S, O'Kane M, Williams L. **Antrim Area Hospital:** Kennedy A. **BaNES NHS primary care trust:** Catchpole S, Wylie S. **Barnet General, London:** Cohen M, Katz J, Kola B, Tanday R, Seenandan J, Steuer L. **Barnsley Hospital NHS Foundation Trust:** Uchegbu E. **Basildon University Hospital:** Mulcahy M. **Bassetlaw Hospital:** Kela R, Woods H. **Bearwood Medical Practice:** Alderman J, Bhanderi S, Matthews J, Newhouse R, Purcell J, Sen Gupta P. **Belfast City Hospital:** Henry RW, McMullan P, Nugent A. **Bensham General Hospital:** Narayanan K R, Razi S, Weaver J. **Birmingham Community Healthcare NHS Trust:** Bhanderi S, Cunningham B, Houghton K, Matthews J, Muralidhara K, Sen Gupta P, Shahid S, Thomas A. **Bradford 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**Monklands Hospital:** Sandeep T C, White A. **Musgrove Park Hospital (Taunton & Somerset NHS Foundation Trust):** Adams S, Andrews R, Close C, Douek I, Dunlop A, Lambert P, Thomas J, Watson J. **New Cross Hospital Wolverhampton:** Katredry V, Khalid Y, Krishnasamy S, Nayak A U, Singh B M. **Newham University Hospital:** Balakumar Y, Gelding S, Menon R, Rayanagoudar G. **NHS Tayside (Ninewells Hospital/Perth Royal Infirmary):** Brennan G, Connagher A, Dutton A, George P, Leese G, Mackie A, Malcom E, McCrimmon R, Morris, Pearson E. **Northumbria Diabetes Service:** Strey C. **Norvic Family Practice (SWBH), Victoria Health Centre:** Baker O, Ely C, Pathan H. **Orpington Hospital:** Allinson R, Casiglia D, Danby T, Fisher N, Hussey S, Lovie K, Lovegrove-Saville L, Mackay F. **Pendyffryn Medical Group, Prestatyn (GP Practice):** Morrison C L. **Pennine Acute Hospitals Trust:** Adams L, Aherne D, Ahmad M, Allen G, Anderson K, Asam M, Atherton L, Balmuri M, Bennion J, Benton M, Berry M J, 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#### Acknowledgment

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# ABCD nationwide exenatide and liraglutide audits

Nationwide contribution to exenatide and liraglutide national audit 2011



- Real-life data
  - >13000 patients from
  - >150 centres
  - >500 contributors
- There had been (by 2018)
  - 12 published papers
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# What did we learn from these audits?

- Combined trials v real world

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- Combined trials v real world

	Clinical trials combined	Real clinical use in UK (ABCD audit)
	Baseline HbA <sub>1c</sub> (%)	
Exenatide	8.37	9.47
Liraglutide	8.5	9.40
	Baseline BMI (kg/m <sup>2</sup> )	
Exenatide	32.72	39.8
Liraglutide	31	39.0

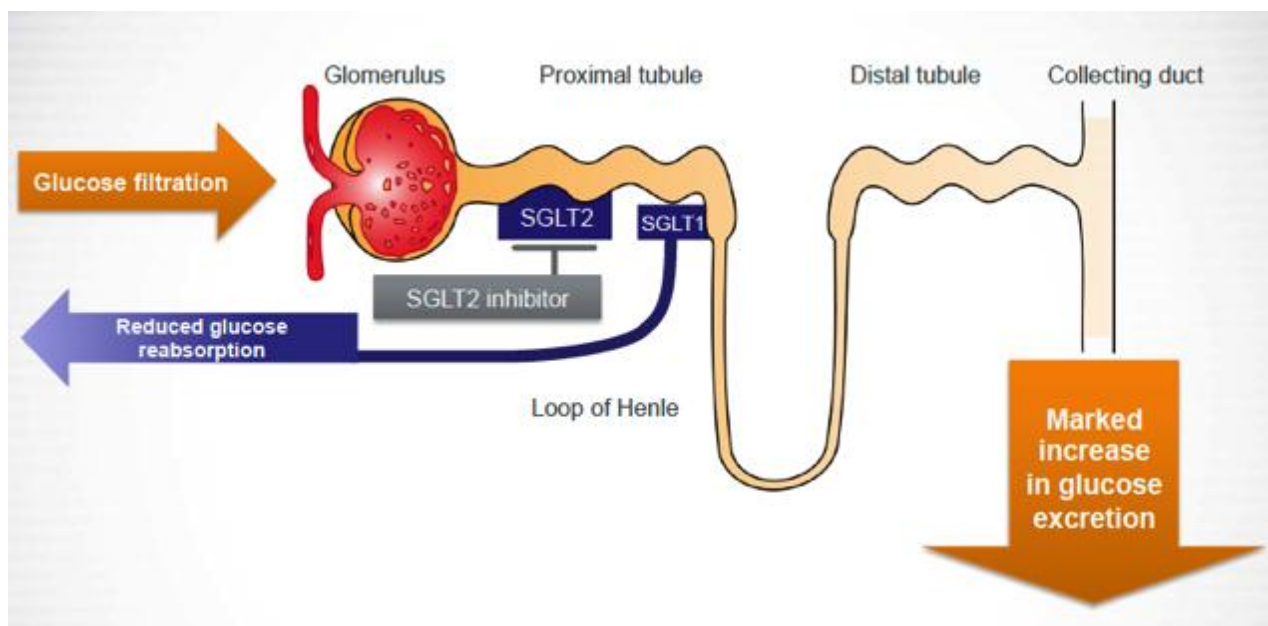
# What did we learn from these audits?

- Combined trials v real world
- Reality versus NICE guidelines
- Off licence use with insulin
- An important safety issue uncovered
- Pancreatitis
- GLP1-RAs in professional drivers
- Liraglutide in renal impairment
- Diabetes and NAFLD – impact on ALT

# What else did we learn from these audits?

- Difference in HbA1c and weight responses – exenatide v liraglutide audits
- Liraglutide with different insulin regimes
- Effectiveness in South Asians
- Liraglutide – predicting treatment response
- Switching to liraglutide from BD exenatide or from DPP-4 inhibitor
- Influence of age and non-use of metformin on GI side effects with liraglutide
- Safety

# SGLT2 inhibitors – a chance to learn in the same way about a new class



- Canagliflozin
- Dapagliflozin
- Empagliflozin

# ABCD nationwide dapagliflozin audit

- Launched October 2014
- Findings so far .....

# Year 1 Audit Overview – October 2015

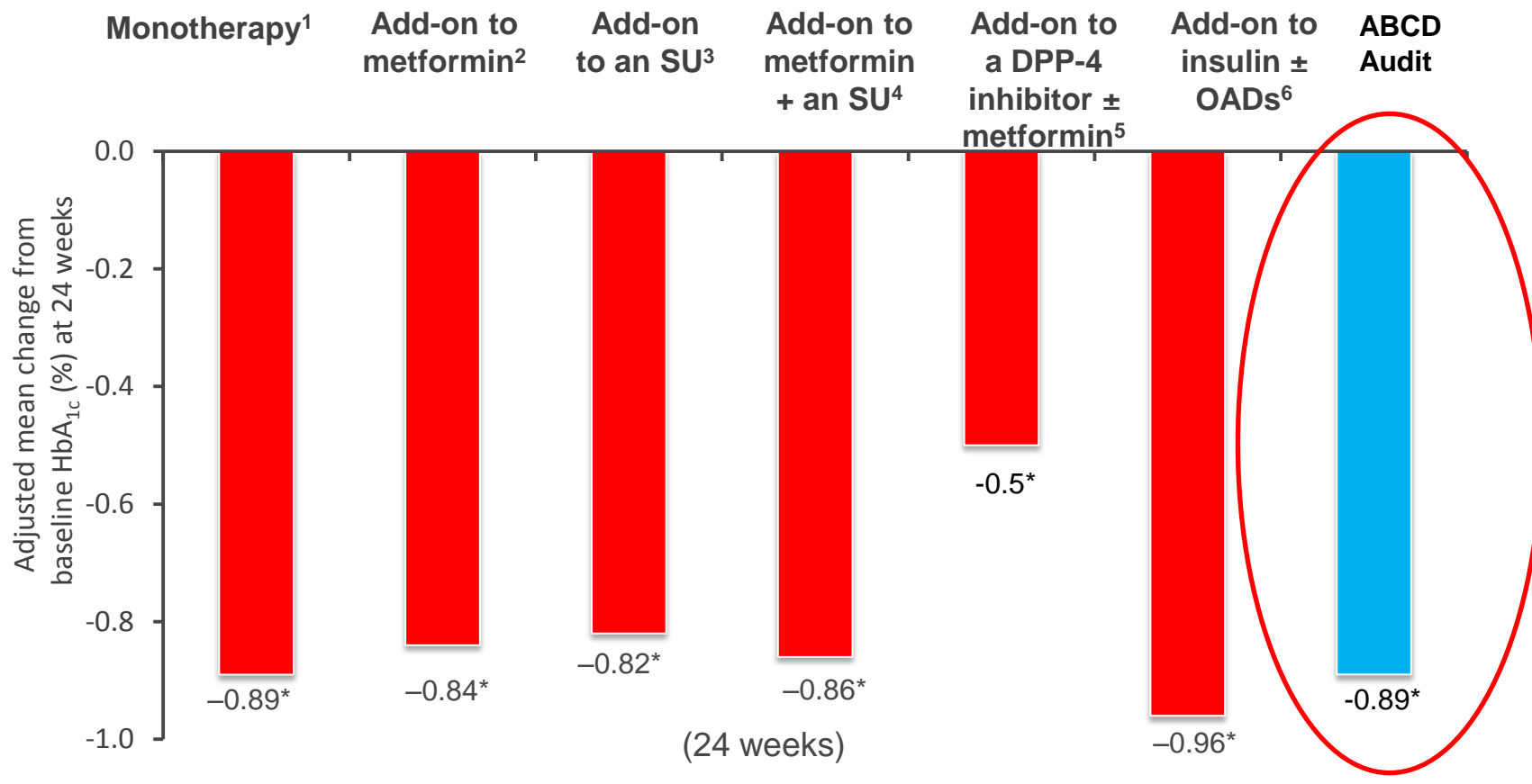
Data Input	Oct 2014 – Oct 2015	
Centres	44	
Contributors	129	
Number of Patients	943	
Age (years)	56.7±10.4	
Sex [Males(%)]	55.9%	
Duration of diabetes (years)*	11.4 (6–16)	
Baseline HbA <sub>1c</sub> (mmol/mol)	80.2±16.1	
Baseline HbA <sub>1c</sub> (%)	9.5±1.5	8.0
BMI (kg/m <sup>2</sup> )	37.0±13.3	32.2
Baseline weight (kg)	103.3±22.7	
Duration of follow up (months)*	6.4 (0–12.3)	

**vs Combined Clinical Trials – Dapagliflozin**

Reported as mean±SD or median (IQR)\*

Data presented at ABCD autumn meeting, November 2015

# Reductions in HbA<sub>1c</sub>: RCT data vs. ABCD audit



Baseline HbA<sub>1c</sub>

8.01%

7.92%

8.07%

8.08%

7.9%

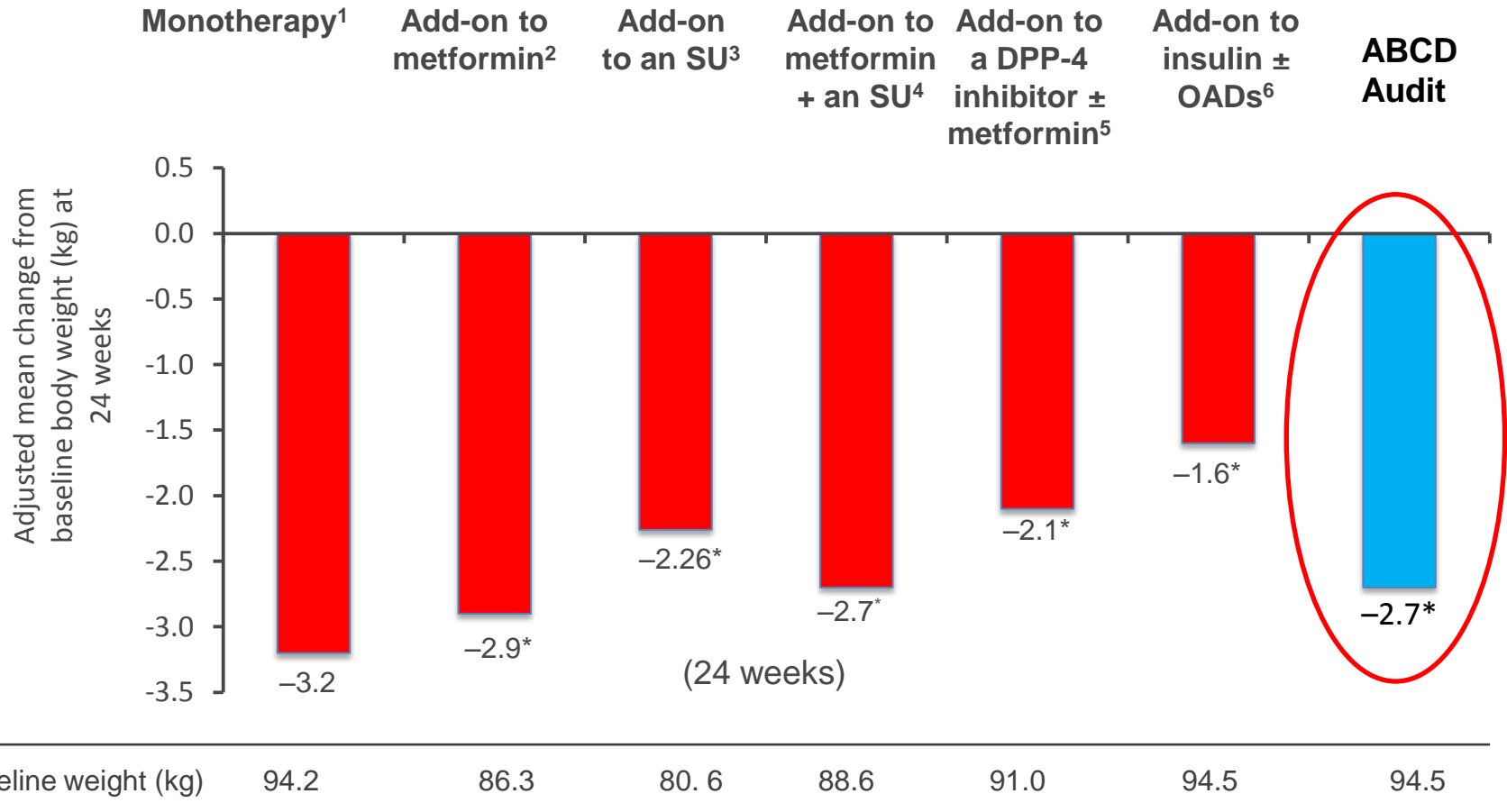
8.57%

9.5%

1. Ferrannini E et al (2010) *Diabetes Care* **33**: 2217–24; 2. Bailey CJ et al (2010) *Lancet* **375**: 2223–33; 3. Strojek K et al (2011) *Diabetes Obes Metab* **13**: 928–38; 4. Matthaes S et al (2015) *Diabetes Care* **38**: 365–72; 5. Jabbour SA et al (2014) *Diabetes Care* **37**: 740–50; 6. Wilding JPH et al (2012) *Ann N Y Acad Sci* **1265**: 405–15

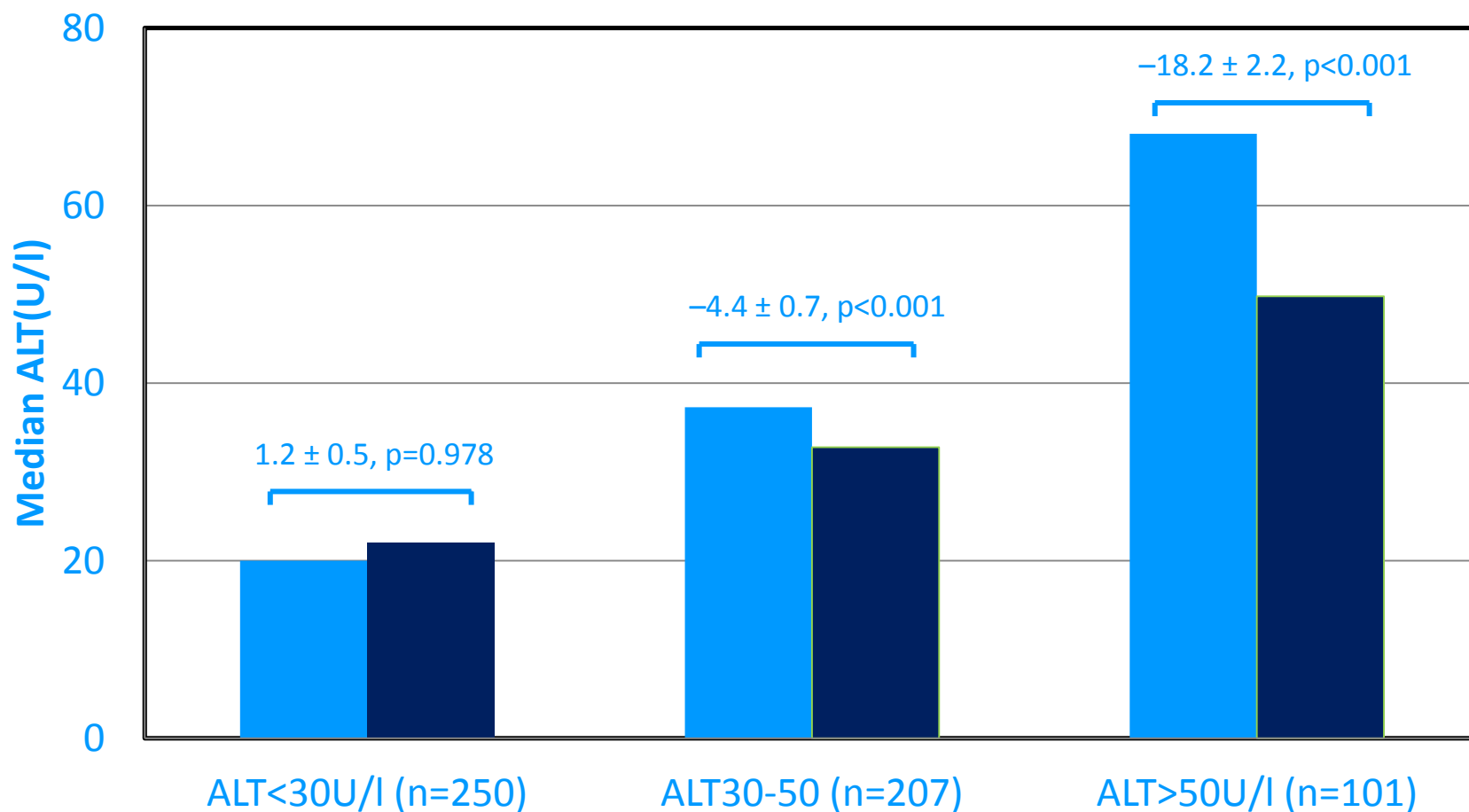


# Weight loss: : RCT data vs. ABCD audit



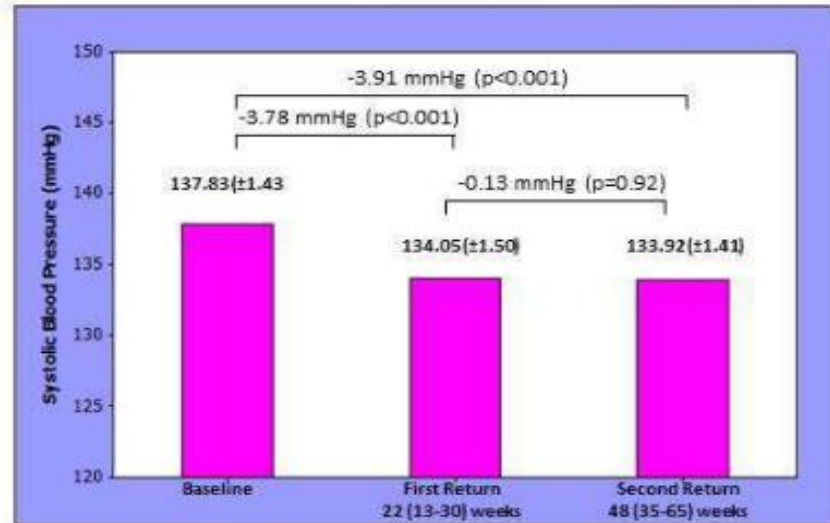
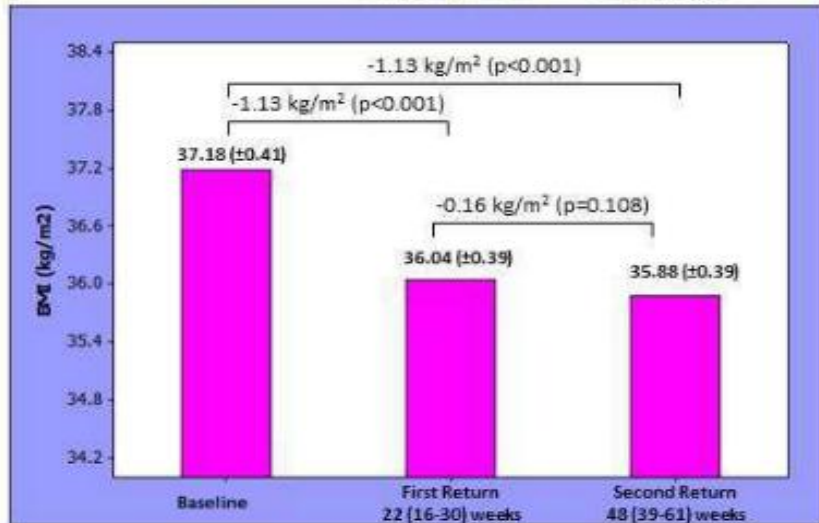
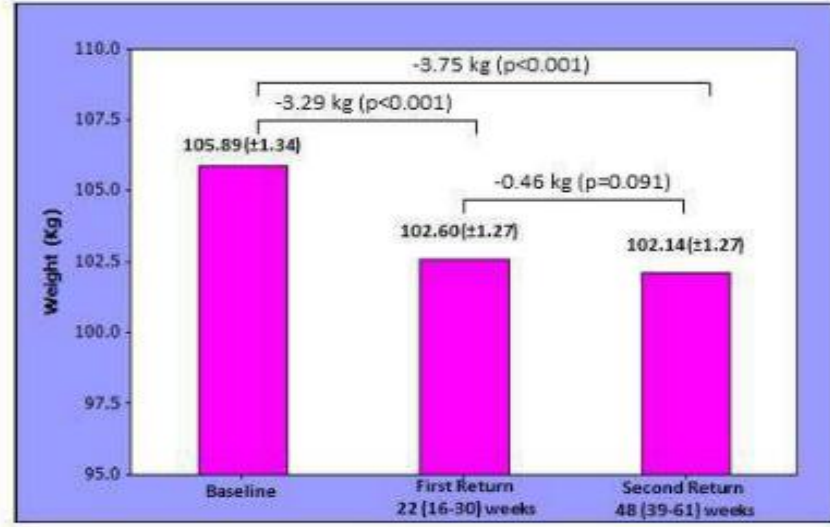
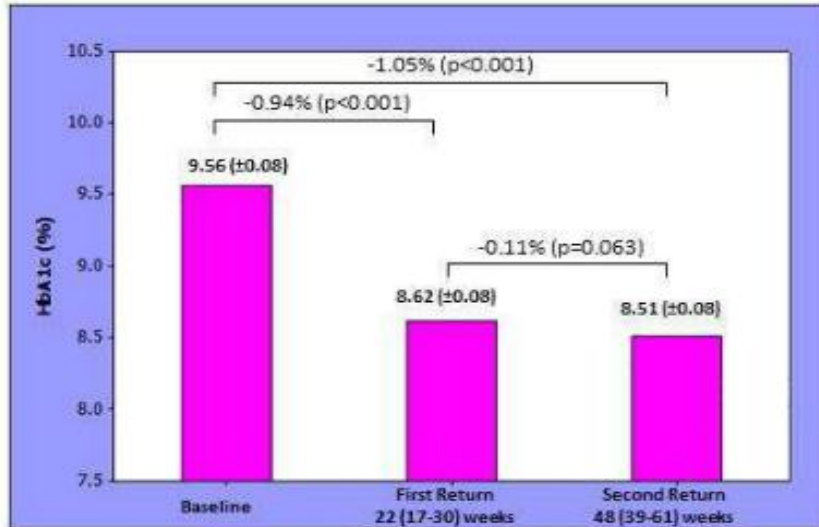
1. Ferrannini E et al (2010) *Diabetes Care* **33**: 2217–24; 2. Bailey CJ et al (2010) *Lancet* **375**: 2223–33; 3. Strojek K et al (2011) *Diabetes Obes Metab* **13**: 928–38; 4. Matthaai S et al (2015) *Diabetes Care* **38**: 365–72; 5. Jabbour SA et al (2014) *Diabetes Care* **37**: 740–50; 6. Wilding JPH et al (2012) *Ann Intern Med* **156**: 405–15;

# ALT response to dapagliflozin



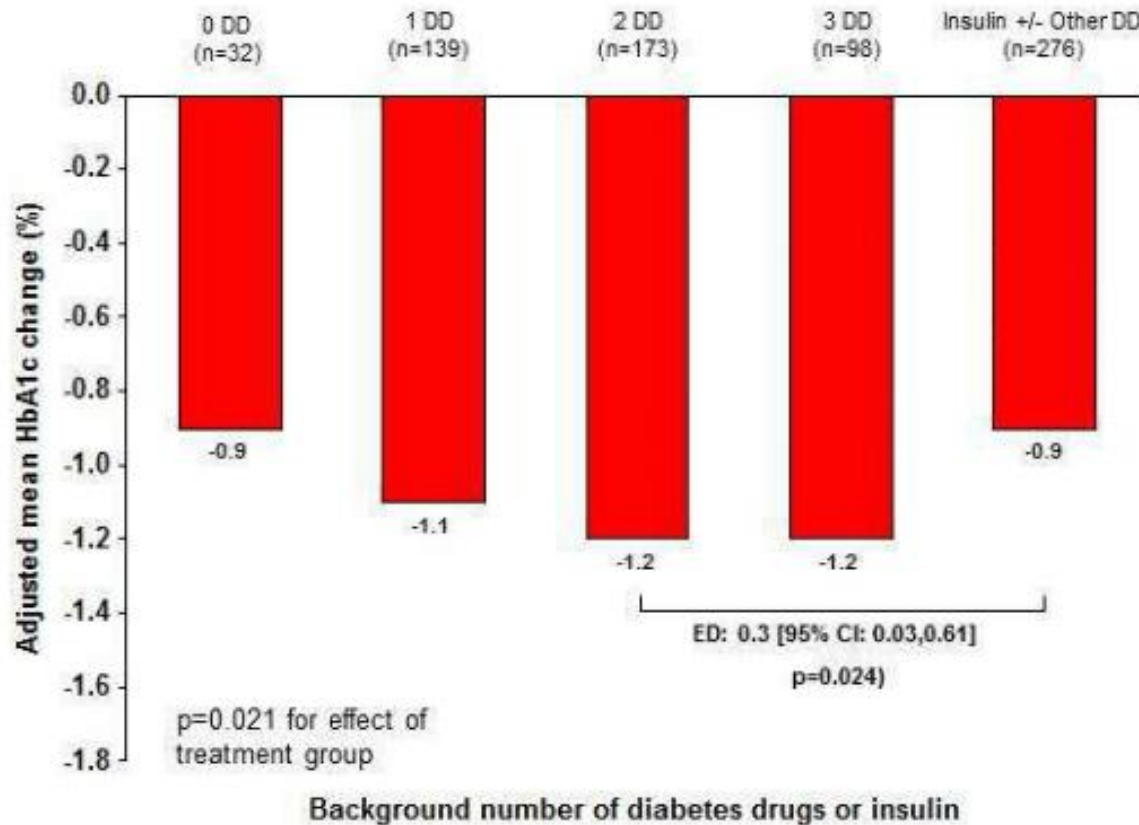
Data presented at DUK annual professional conference, Glasgow, March 2016

# Dapagliflozin – improvements sustained



Data presented at ADA meeting, New Orleans, June 2016

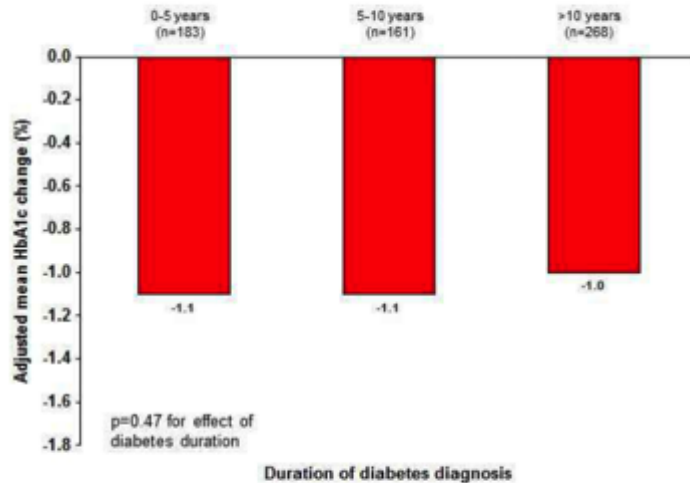
Figure 1: Change in HbA1c stratified by background diabetes therapy



Data are adjusted mean and estimated difference (ED) were analysed by ANCOVA with baseline HbA1c and eGFR as covariates. DD; diabetes drugs

# ABCD dapagliflozin audit

Figure 2: Change in HbA1c stratified by duration of diabetes

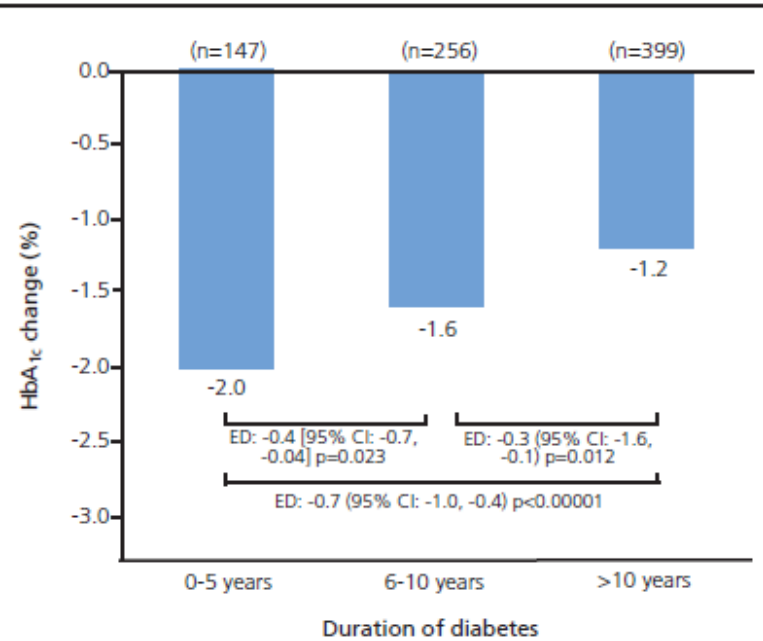


Data are adjusted mean analysed by ANCOVA with baseline HbA1c and eGFR as covariates.

Data presented at ADA meeting, New Orleans, June 2016

# ABCD liraglutide audit

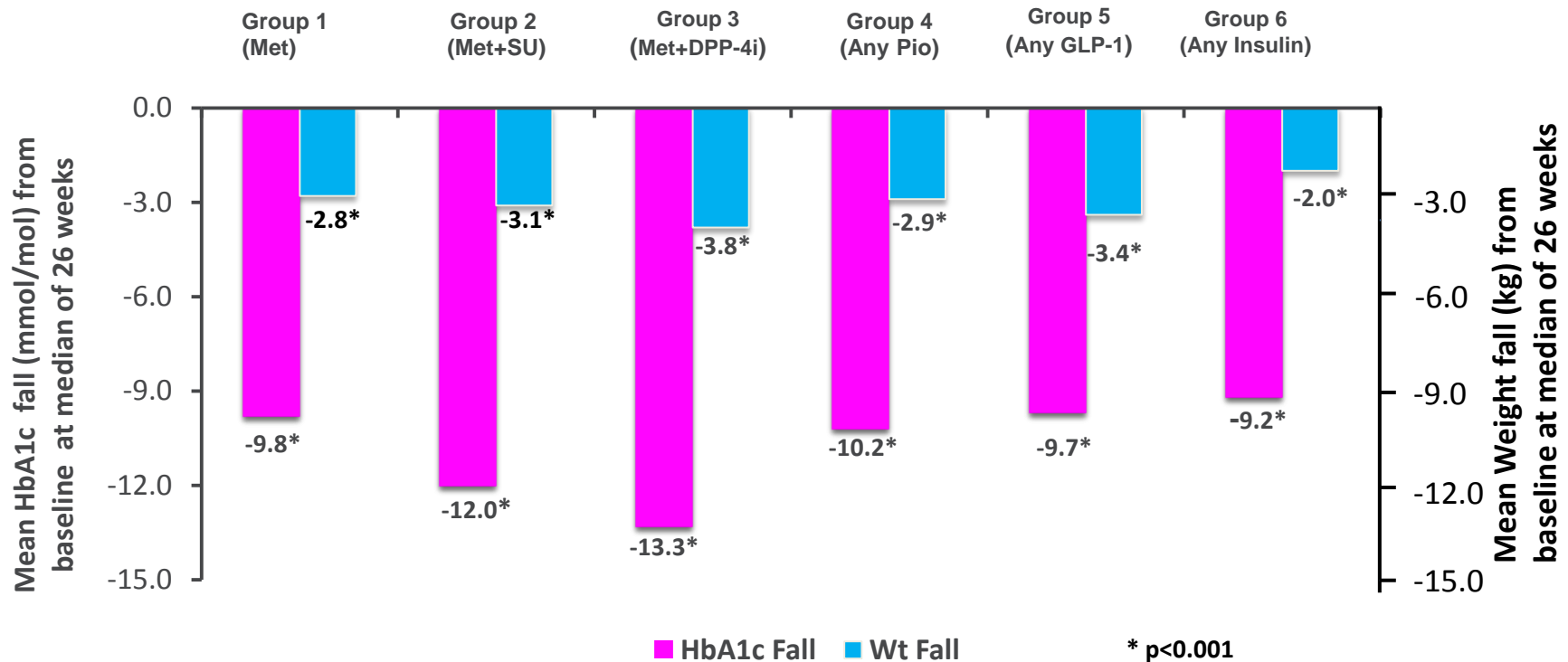
Figure 2. Mean HbA1c changes after 26 weeks of liraglutide treatment, stratified according to duration of diabetes



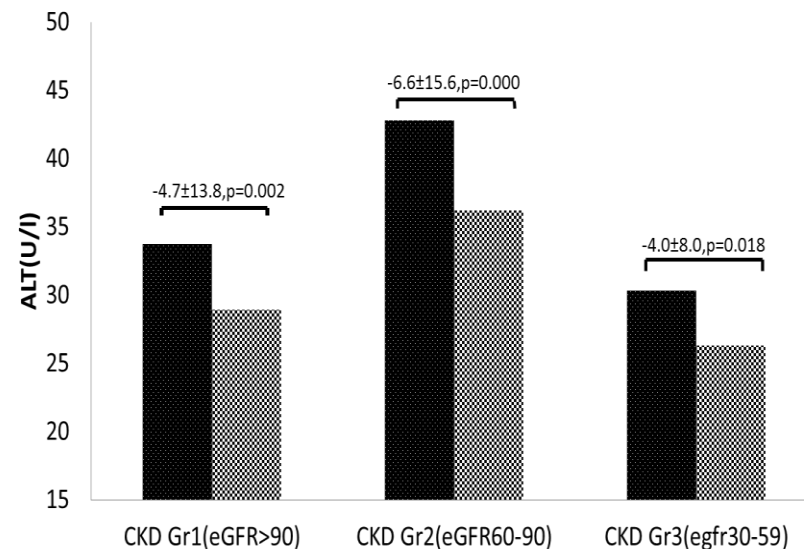
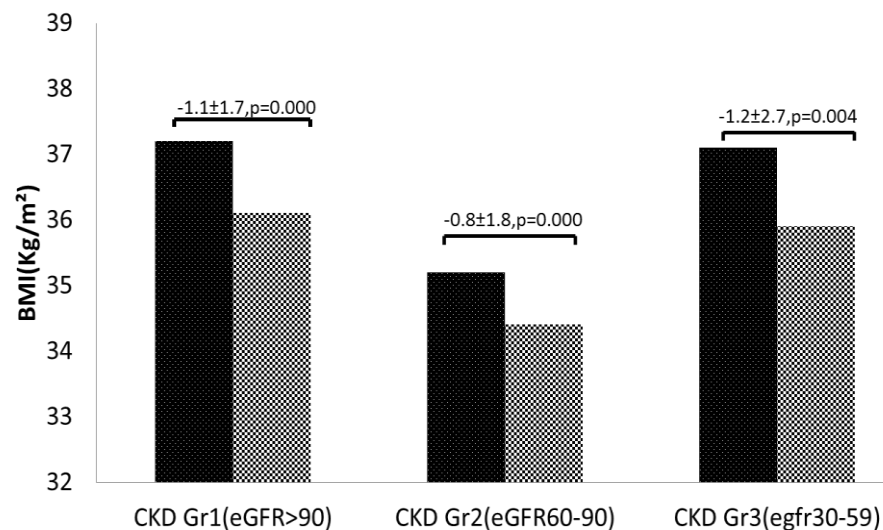
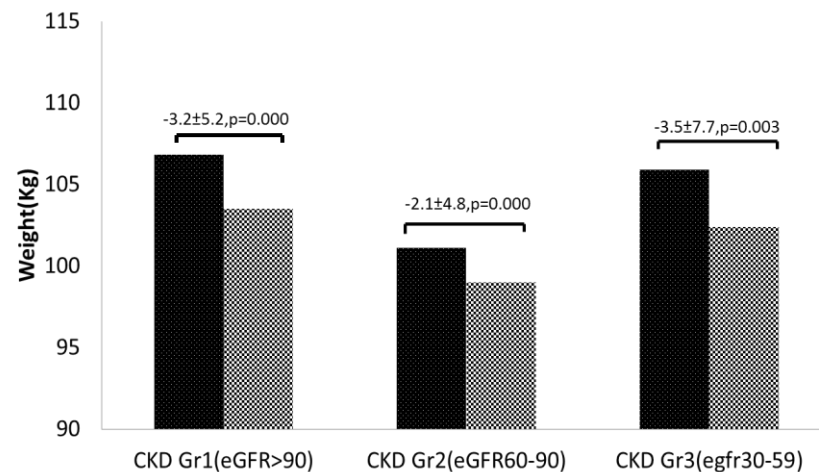
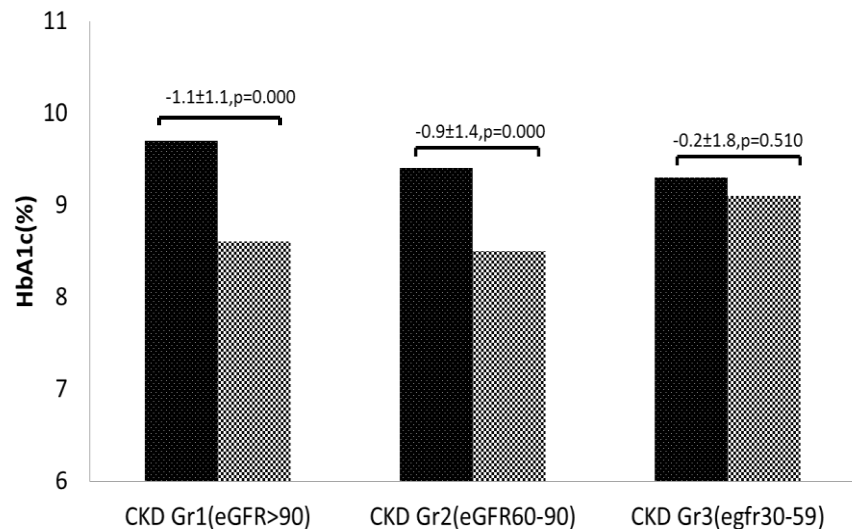
Columns show adjusted mean changes analysed by ANCOVA with baseline HbA1c as a covariate. ED: estimated difference; CI: confidence interval

Thong KY et al. Br J Diabetes Vasc Dis 2015; 15(4): 169–172

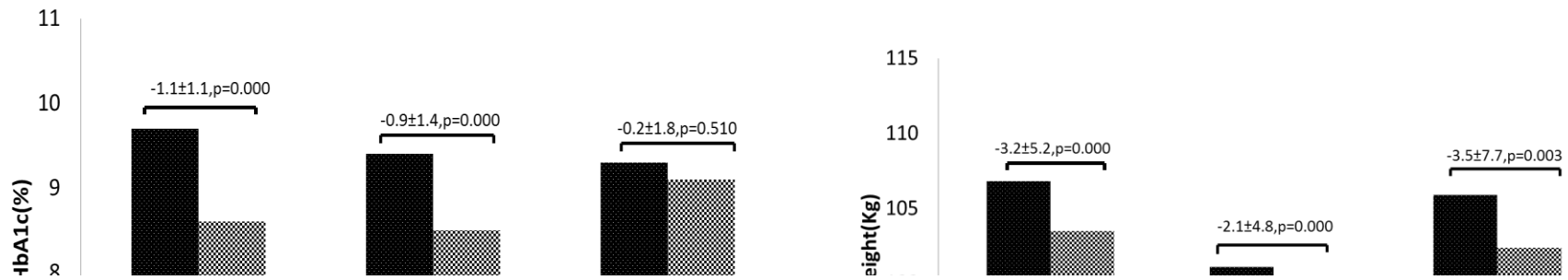
# Effect of dapagliflozin on HbA1c and weight after its addition to various combinations of other diabetes medications: ABCD nationwide dapagliflozin audit\*



\* EASD 2016 Poster Presentation: M. Yadagiri, P. Sen Gupta, R.E.J. Ryder et al on behalf of all ABCD nationwide dapagliflozin audit contributors



Data presented at ADA meeting, San Diego, June 2017



## Conclusion

- Dapagliflozin reduces HbA1c, weight, BMI, systolic BP and ALT by statistically and clinically significant amounts in normal and mild renal impairment
- In moderate renal impairment, there is a reduction in weight and ALT but has no significant impact on HbA1c or systolic BP



Data presented at ADA meeting, San Diego, June 2017



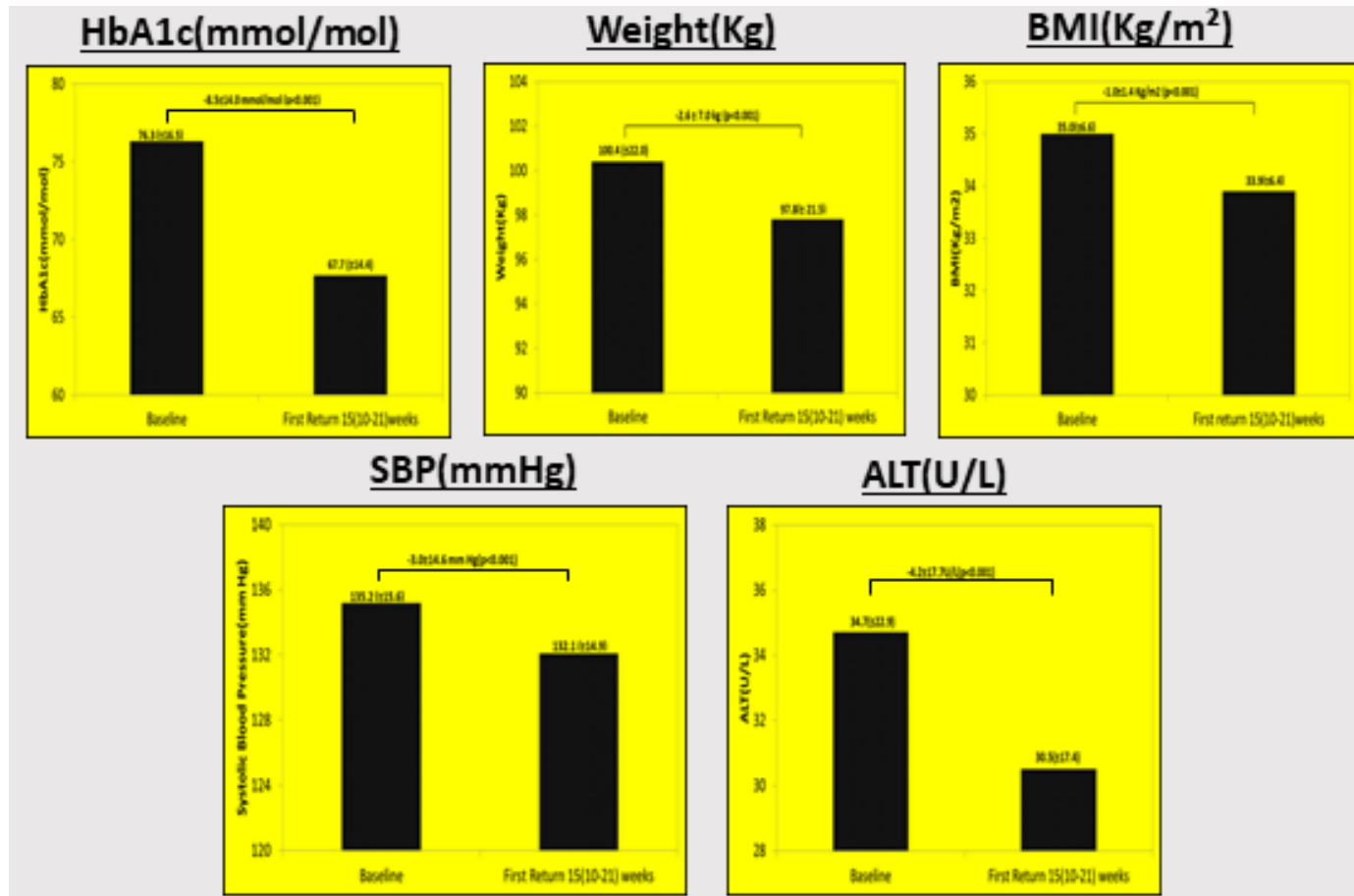
# ABCD nationwide Canagliflozin audit

- Launched January 2016
- Findings so far .....

# ABCD nationwide Canagliflozin audit – findings so far

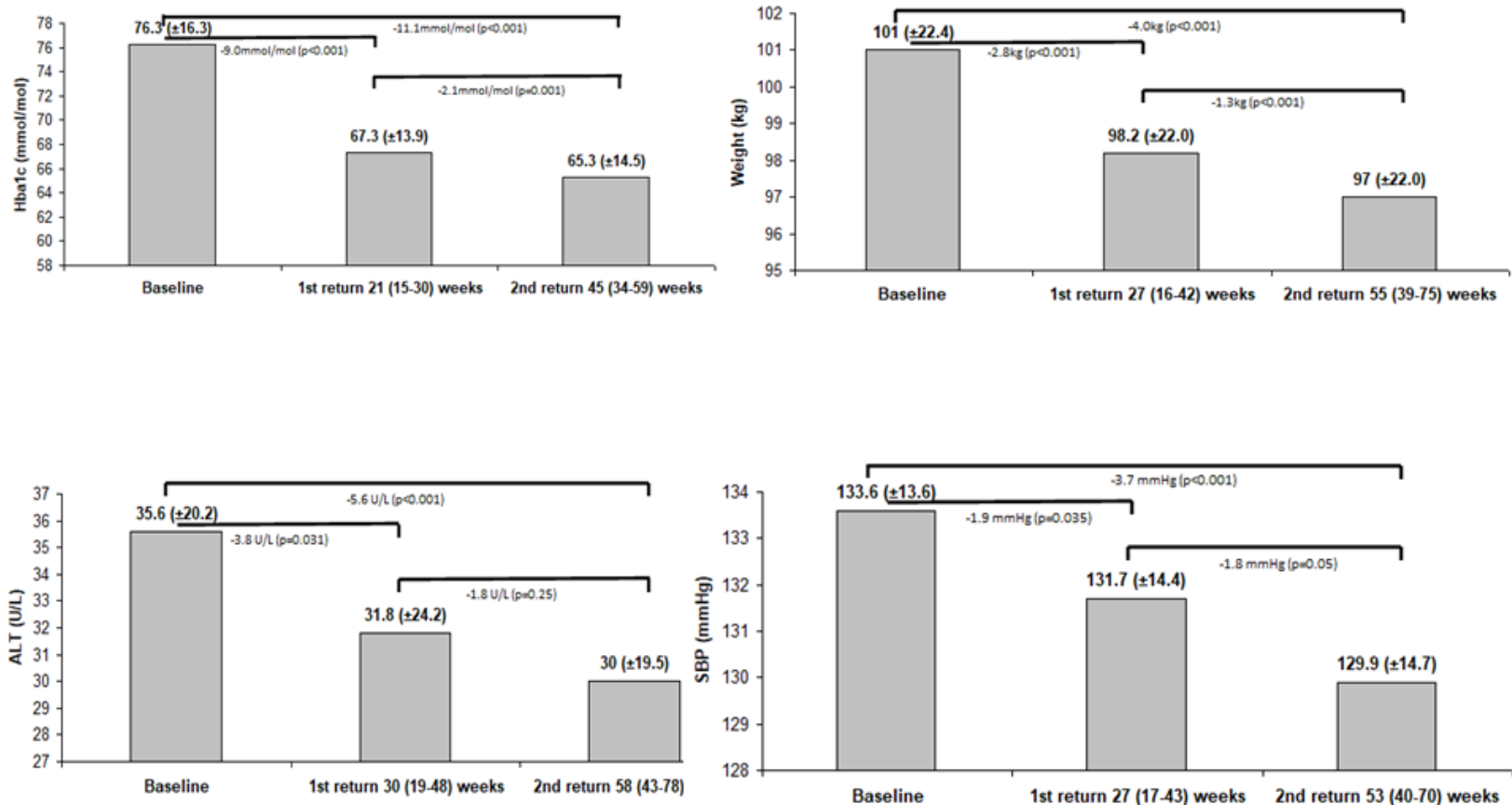


# Canagliflozin audit – first return



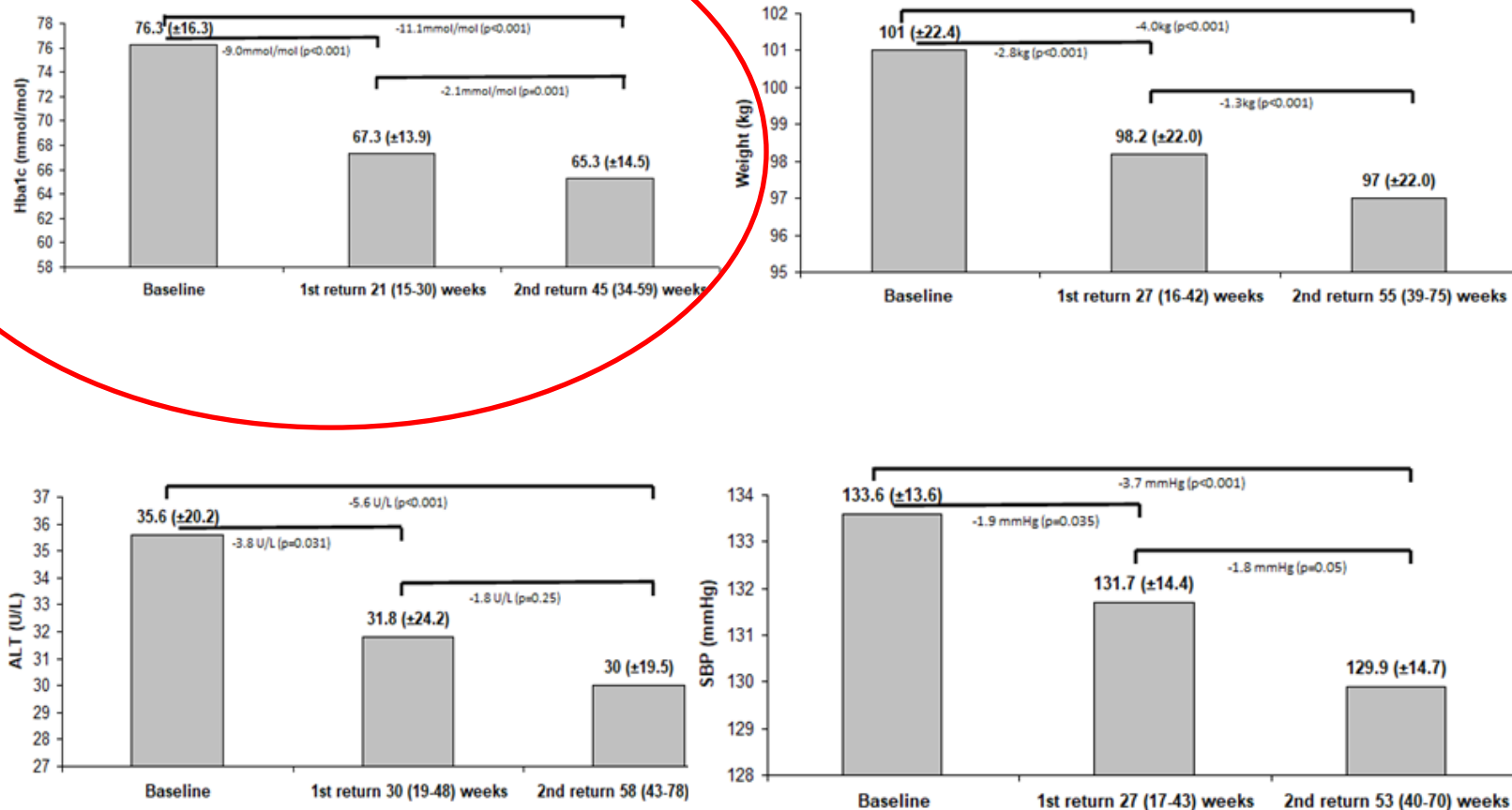
Data presented at EASD meeting, Lisbon, September 2017

# Canagliflozin audit – further improvement between first and second return



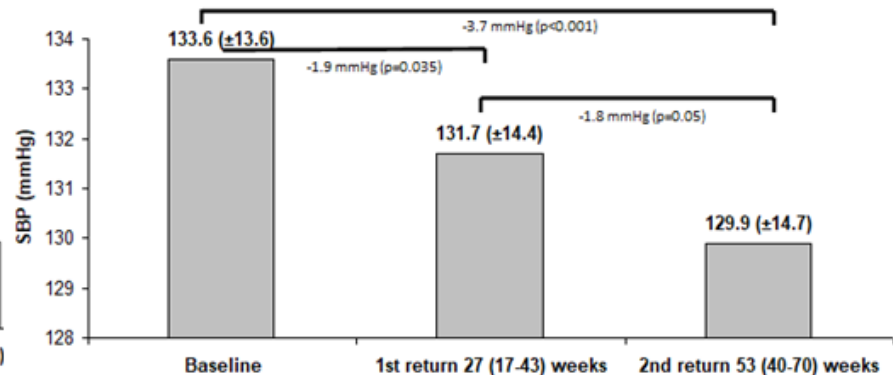
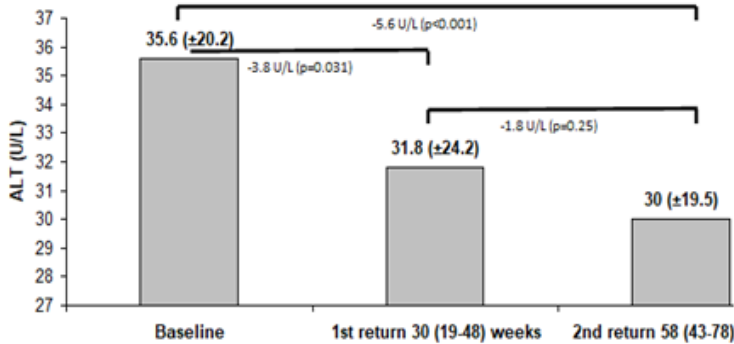
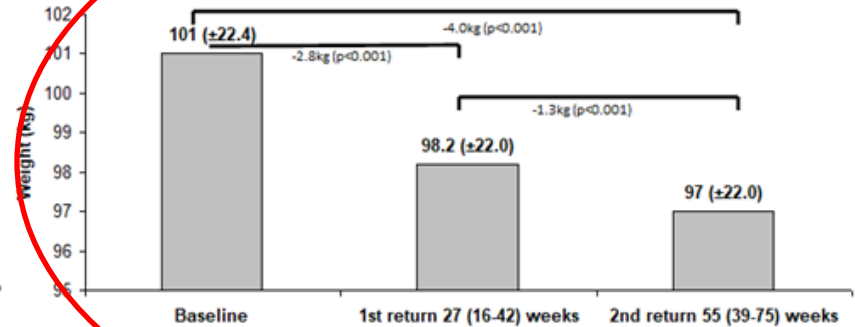
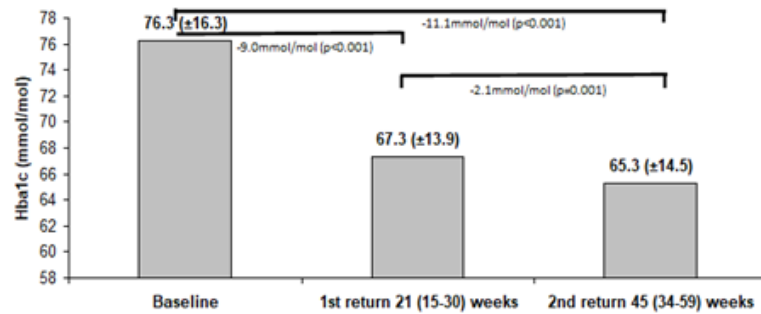
**Figure:** Mean (±SD) HbA1c (n=297) , weight (n=242), ALT (n=177) and systolic blood pressure (n=285), baseline vs first and second return (after median (interquartile range) weeks) to clinic following commencement of canagliflozin.

# Canagliflozin audit – further improvement between first and second return



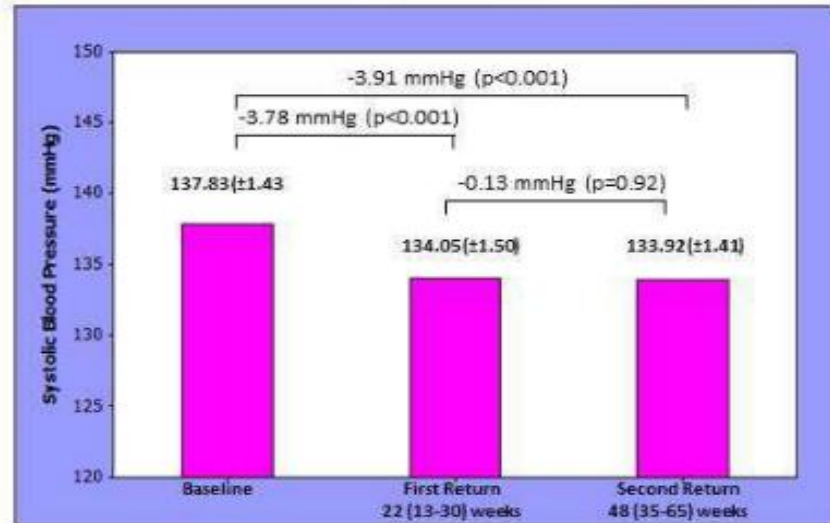
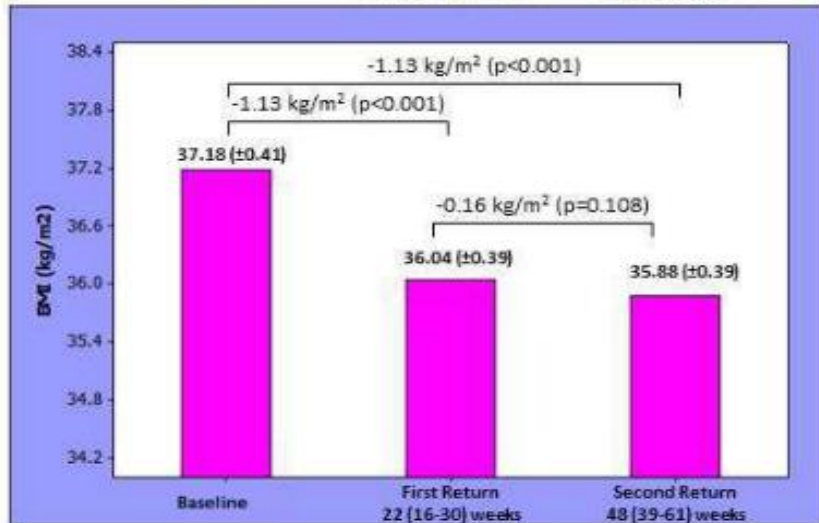
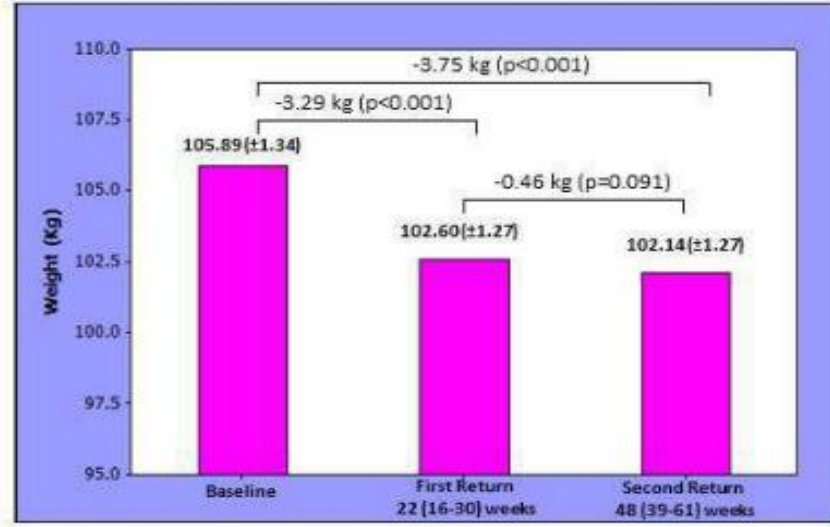
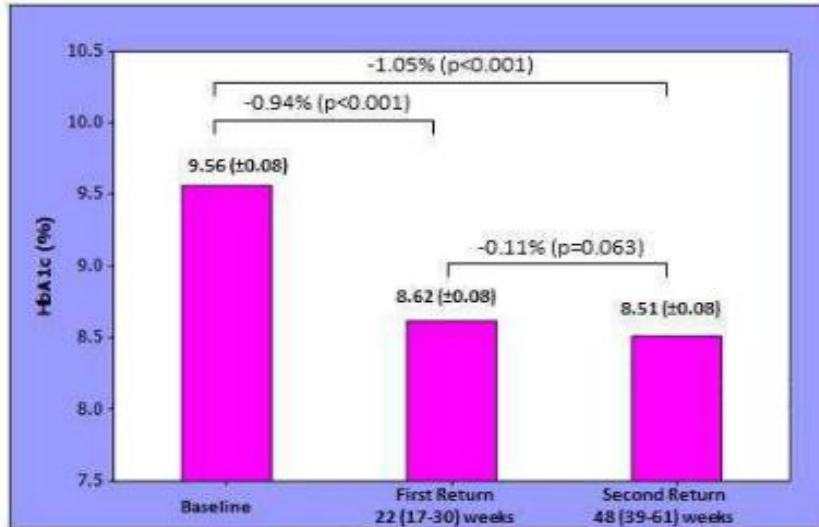
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# Canagliflozin audit – further improvement between first and second return



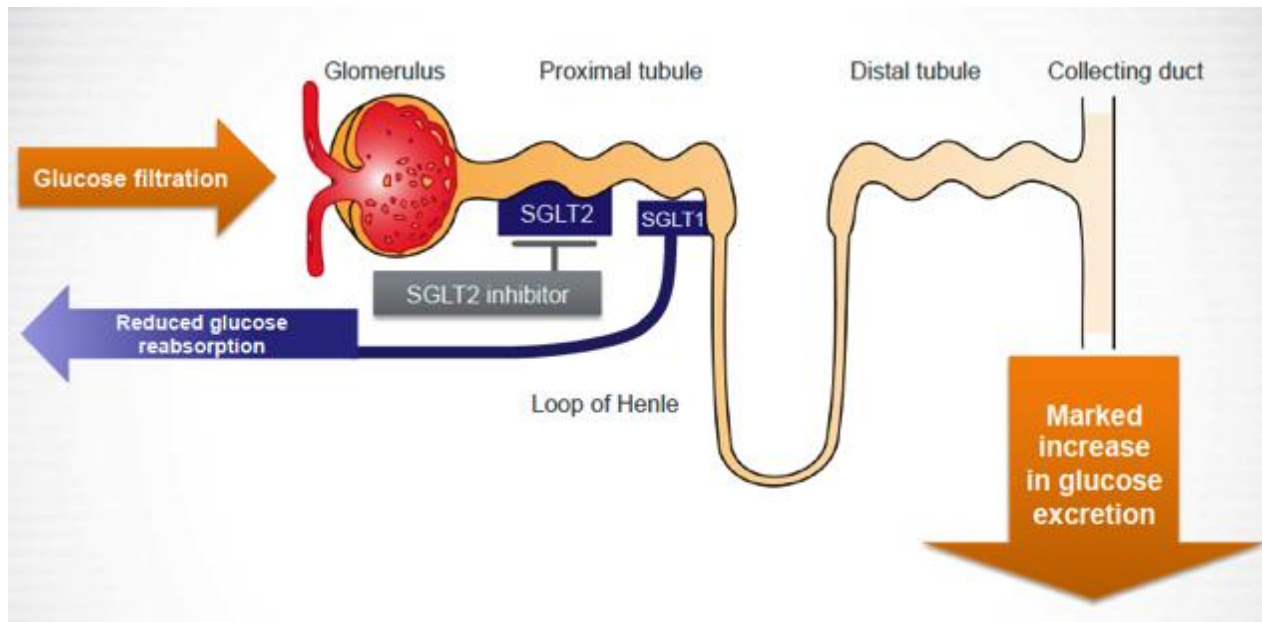
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# Dapagliflozin – improvements sustained



Data presented at ADA meeting, New Orleans, June 2016

# SGLT2 inhibitors – a chance to learn in the same way about a new class



- Canagliflozin
- Dapagliflozin
- **Empagliflozin**



# ABCD nationwide degludec audit



**Association of British Clinical Diabetologists**  
*Degludec* Nationwide Audit

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## ABCD nationwide Insulin degludec audit

**About the ABCD nationwide degludec audit**

This audit follows on from the success of the ABCD nationwide *exenatide*, *liraglutide*, *exenatide QW*, and *dapagliflozin* audits. With many older established insulins in common usage, it will be important to try to gain insight into degludec in real clinical practice by attempting to record the routine data on all patients treated with this new insulin. If possible, so that the most accurate picture of it can be obtained. By pooling the data nationally we will all learn more quickly from the shared experience. In clinical trials degludec was associated with less hypoglycaemia than other insulins and allowed for flexible dosing. There was less intra-subject variability than with glargine. Potentially therefore patients with very variable patterns of home blood glucose monitoring, particularly overnight and fasting, may benefit from a switch to insulin degludec. The audit may give insight into whether these potential advantages translate in real clinical practice. The tool will be hosted on a tool very similar to that used in the *liraglutide* audit and as those taking part in that audit will find it particularly easy. The audit will launch in conjunction with the Autumn ABCD meeting, November, 2014 and has a number of objectives.

Register for the audit  
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Degludec audit objectives  
Order preprinted data entry forms  
Download first visit data entry forms  
Download follow up visit data entry forms  
Further information, contact us  
Main ABCD homepage

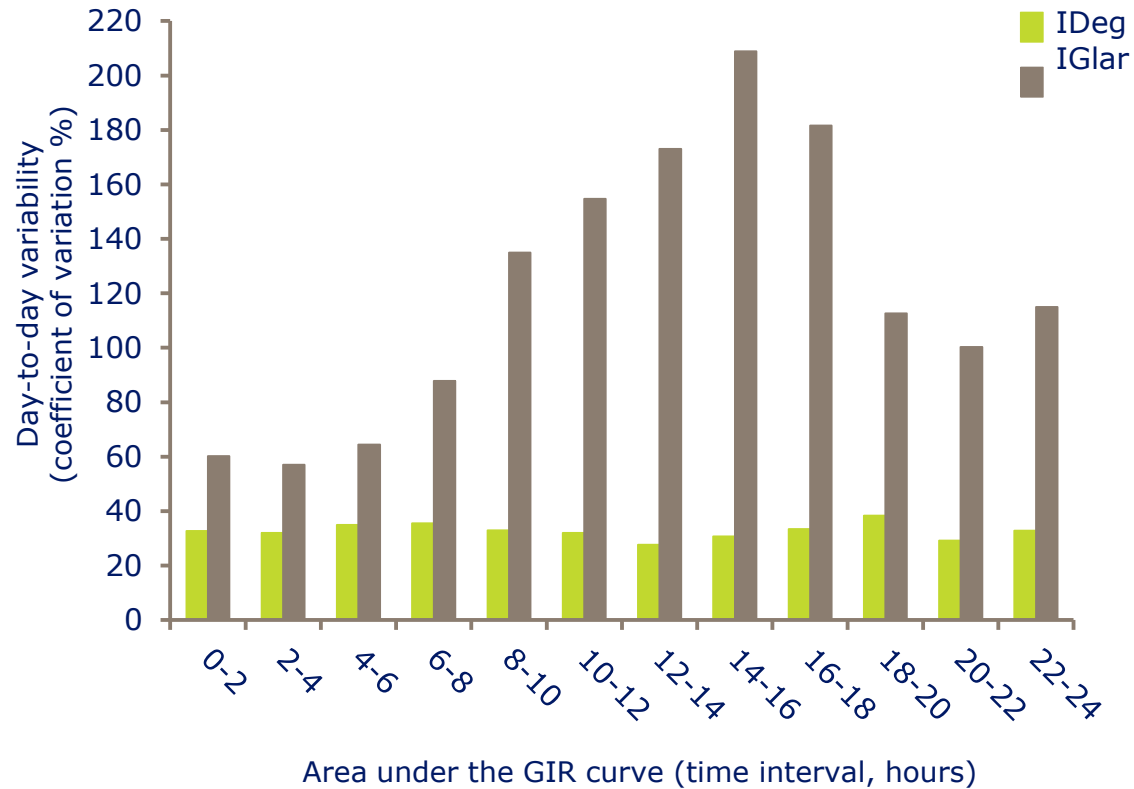
Collect data on-line or via paper forms

The degludec on-line audit tool is so easy to use that live data entry in clinic is a real option to be considered. Otherwise to facilitate data collection during clinics there are two paper forms which exactly match the data that can be entered into the audit tool. You can download and print these forms locally or order pre-printed data entry forms.

To download the forms to printout for use, use the following links:

- Even if you have only a couple of patients
- If everyone contributes their couple of patients....
- We must aim to get every degludec patient in the UK in the audit

# Variability in glucose-lowering effect over 24 hours at steady state



Endpoint	IDeg CV (%)	IGlax CV (%)	<i>p</i> value
AUC <sub>GIR,0-24h</sub>	20	82	<i>p</i> < 0.0001

# Degludec audit - reasons for switching to degludec from another basal insulin

## RATIONALE FOR STARTING DEGLUDEC? (Please tick all that apply)

- |   |                                      |                                     |
|---|--------------------------------------|-------------------------------------|
| Problems with hypoglycaemia   | <input checked="" type="radio"/> Yes | <input type="radio"/> No            |
| Poor compliance, e.g. need flexible injection timing  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| Need of more than 80 IU/day   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| Needs OD basal insulin  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| Considering going into a pump   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| To fit in with variably timed visit by third party to administer (eg district nurse, relative...) | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| Intrasubject variability of glucoses with current basal insulin                                   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| <input type="text" value="Intra variability in absorption"/>                                      | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |

Screenshot from the ABCD degludec nationwide audit on-line form

# Effect of insulin degludec on hypoglycaemia

Change in frequency of hypoglycaemia where reason for switching to insulin degludec was hypoglycaemia

		Reduced	Same	Increased	P value
T1DM	Minor	31	16	0	p < .000001
	Severe	16	13	1	P < 0.01
	Nocturnal	22	12	0	P < .00001
T2DM	Minor	12	12	2	p < .05
	Severe	2	12	0	ns
	Nocturnal	7	12	1	ns

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# Effect of insulin degludec on HbA1c

Change in HbA1c (mmol/mol) after switching to insulin degludec from another basal insulin

Type of diabetes	T1D		T2D	
Reason for degludec	Hypoglycaemia	Other	Hypoglycaemia	Other
n	100	41	40	100
HbA1c before degludec	68.2 ± 20.4	87.4 ± 24.4	64.1 ± 18.4	87.9 ± 23.0
HbA1c after degludec	69.5 ± 22.2	80.2 ± 22.5	61.6 ± 18.5	76.1 ± 22.4
<b>Change in HbA1c</b>	<b>+1.0 ± 1.3 (ns)</b>	<b>-7.2 ± 1.9 * (p &lt; .001)</b>	<b>-2.34 ± 1.8 (ns)</b>	<b>-11.8 ± 2.4 * (p &lt; .00001)</b>

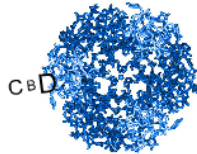
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# ABCD nationwide IDegLira audit



Association of British  
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*IDegLira* Nationwide Audit



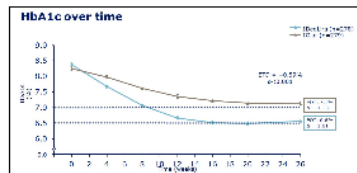
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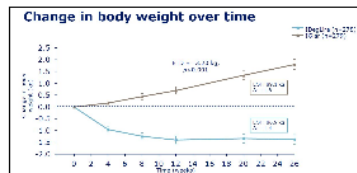
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Above - in clinical trials, HbA1c reduction was considerably more for IDegLira compared to insulin glargine used in a treat to target algorithm. The audit may give insight into whether this advantage translates into real clinical practice - [click to enlarge](#)



Above - in clinical trials, body weight increased with insulin glargine used in a treat to target algorithm, whereas with IDegLira body weight decreased. The audit may give insight into whether this advantage translates into real clinical practice - [click to enlarge](#)

## ABCD nationwide IDegLira audit

### About the ABCD nationwide IDegLira audit

This audit follows on from the success of the [previous ABCD nationwide audits](#) of GLP1 receptor agonists, SGLT2 inhibitors, and [insulin degludec](#). The clinical trials of IDegLira seem to show in those uncontrolled on basal insulin (20-50units), IDegLira showed statistically improved HbA1c reductions in comparison to the up titration of insulin glargine U100 with fewer hypoglycaemic episodes and less weight gain, and indeed with weight loss - see slides on the left for examples of the data concerned. Also in clinical trials, when iDegLira was compared to liraglutide in patients uncontrolled on OADs or to unchanged maximum tolerated GLP-1 (liraglutide or exanetide bd) results showed statistically improved HbA1c and FPG control with fewer gastrointestinal side effects but higher rates of hypoglycaemia and less weight reduction in one trial and weight increase in another. We hope through this nationwide audit to find out if these findings from the clinical trials translate into the same advantages when the agent is used in real clinical practice. The audit will be hosted on a tool very similar to that used in the [liraglutide audit](#) and the [degludec audit](#) so the many contributors taking part in those audits will find it particularly easy. The audit will launch in February or March, 2017, and has a number of [objectives](#).

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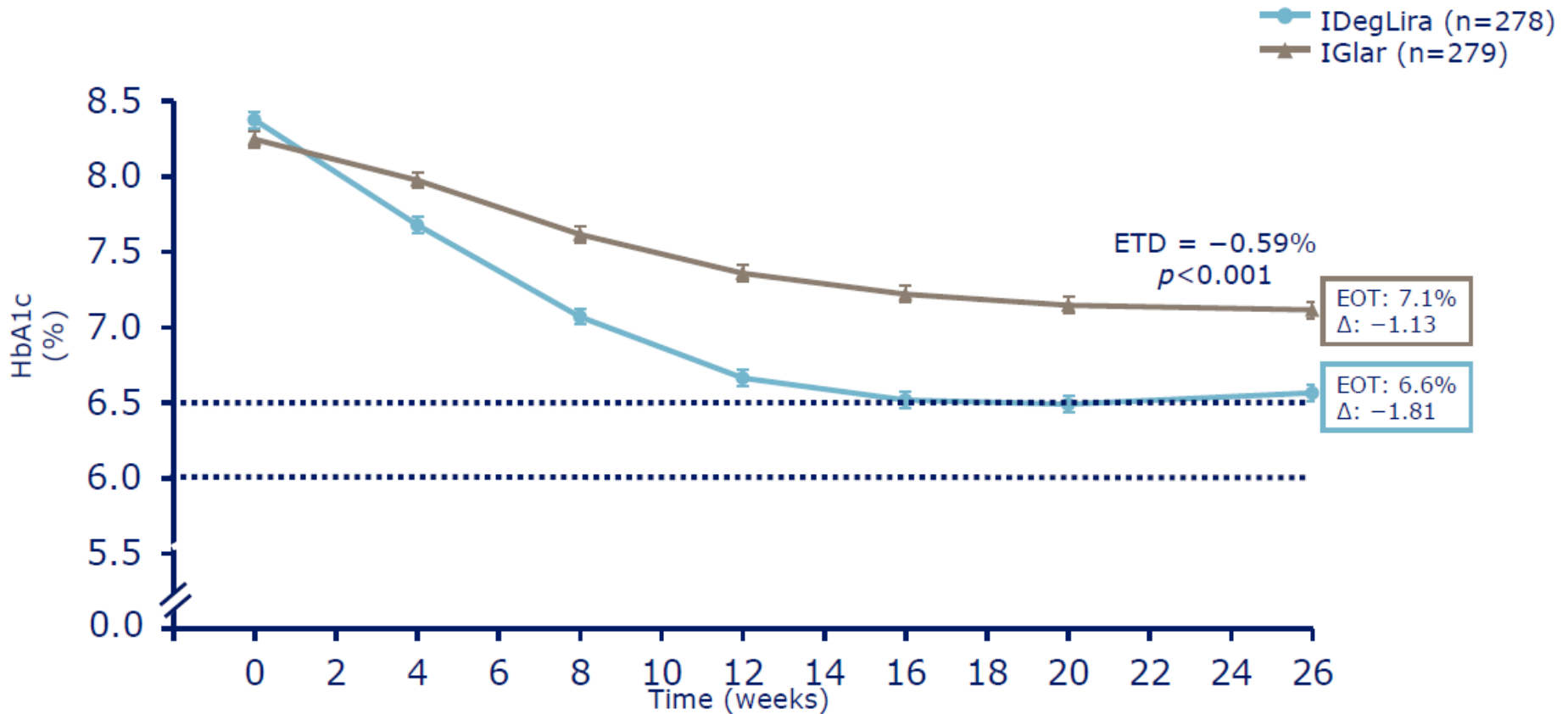
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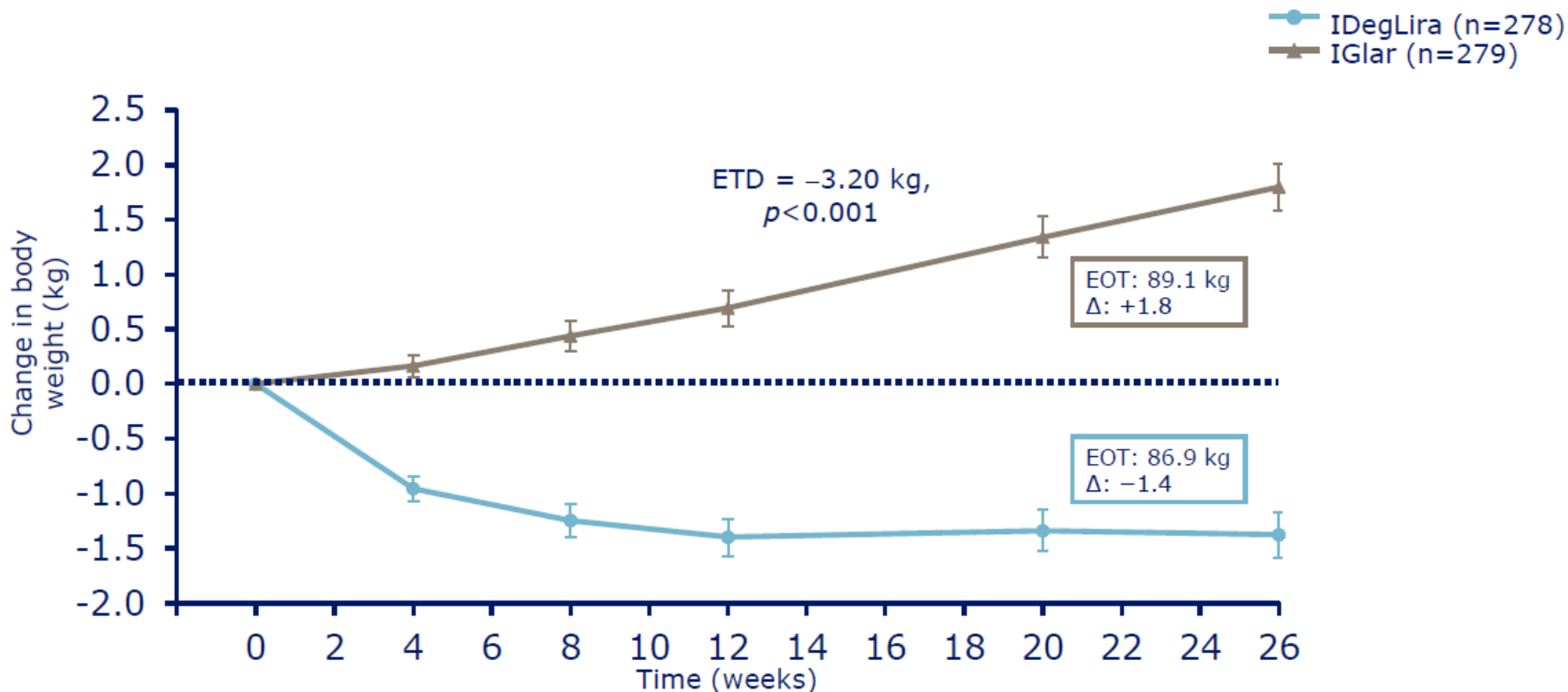
# Treat to Target – IDegLira Vs Glargine

## HbA<sub>1c</sub> over time



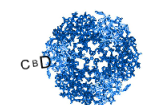
# Treat to Target – IDegLira Vs Glargine

## Change in body weight over time



IDegLira is not licensed for weight loss. Change in bodyweight from baseline was a secondary endpoint in DUAL V, a 26 week study.

# ABCD nationwide IDegLira audit

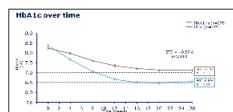


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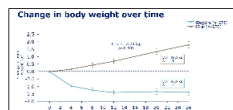
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Above - in clinical trials, HbA1c reduction was considerably more for IDegLira compared to insulin glargine used in a treat to target algorithm. The audit may give insight into whether this advantage translates into real clinical practice - click to enlarge



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# Getting involved: All contributors listed in all output

**ABCD nationwide and worldwide dapagliflozin audit contributors** *The following are those whom we know about.*

**ABCD nationwide dapagliflozin audit – initial setup, maintenance and nationwide analysis:** Ryder REJ, Adamson K, Bailey CJ, Walton C, Thong KY, Sen Gupta P, Cull ML, Yadagiri M. Statistician: Blann A

## England

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# Top contributors are made co-authors – e.g. the latest liraglutide audit paper

## **Insulin treatment and longer diabetes duration both predict poorer glycaemic response to liraglutide treatment in type 2 diabetes: the Association of British Clinical Diabetologists Nationwide Liraglutide Audit**

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<sup>15</sup>Appendix 1

# Top contributors are made co-authors – e.g. the latest dapagliflozin audit paper



## Original research

### **Clinical risk factors predicting genital fungal infections with sodium–glucose cotransporter 2 inhibitor treatment: The ABCD nationwide dapagliflozin audit**

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## 5. Conclusion

Women and patients with previous genital fungal infections are at higher risk of developing genital fungal infections with dapagliflozin treatment. A history of genital fungal infection should be routinely obtained when considering SGLT2 inhibitor treatment, and women should be given closer con-

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## Appendix A.

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# Eclipse project



- Eclipse is a clinical database utilised by some CCGs for their clinical data management.
- Through the efforts of Ian Gallen, a way has been developed for easy extraction of anonymised clinical data with regard to the diabetes medications that are under audit in the ABCD projects.
- So far 4 CCG's and their neighbouring hospitals have signed up to join the ABCD nationwide audit programme providing their data
  - Royal Berkshire Hospital NHS Trust
  - Yeovil Hospital NHS Trust
  - Cheltenham General Hospital
  - Princess Alexandra Hospital, Harlow
- If your CCG uses Eclipse please speak to me during the meeting or contact me at [bob.ryder@nhs.net](mailto:bob.ryder@nhs.net)

# ABCD Nationwide FreeStyle Libre Audit



On-line audit tool in final stages of preparation – full go live shortly

# Please be active in the current ABCD audits



Especially:

- Canagliflozin
- Empagliflozin
- **Degludec**
- **IDegLira**
- **FreeStyle Libre**