

Strategic Plans: Protein Analysis Working Group

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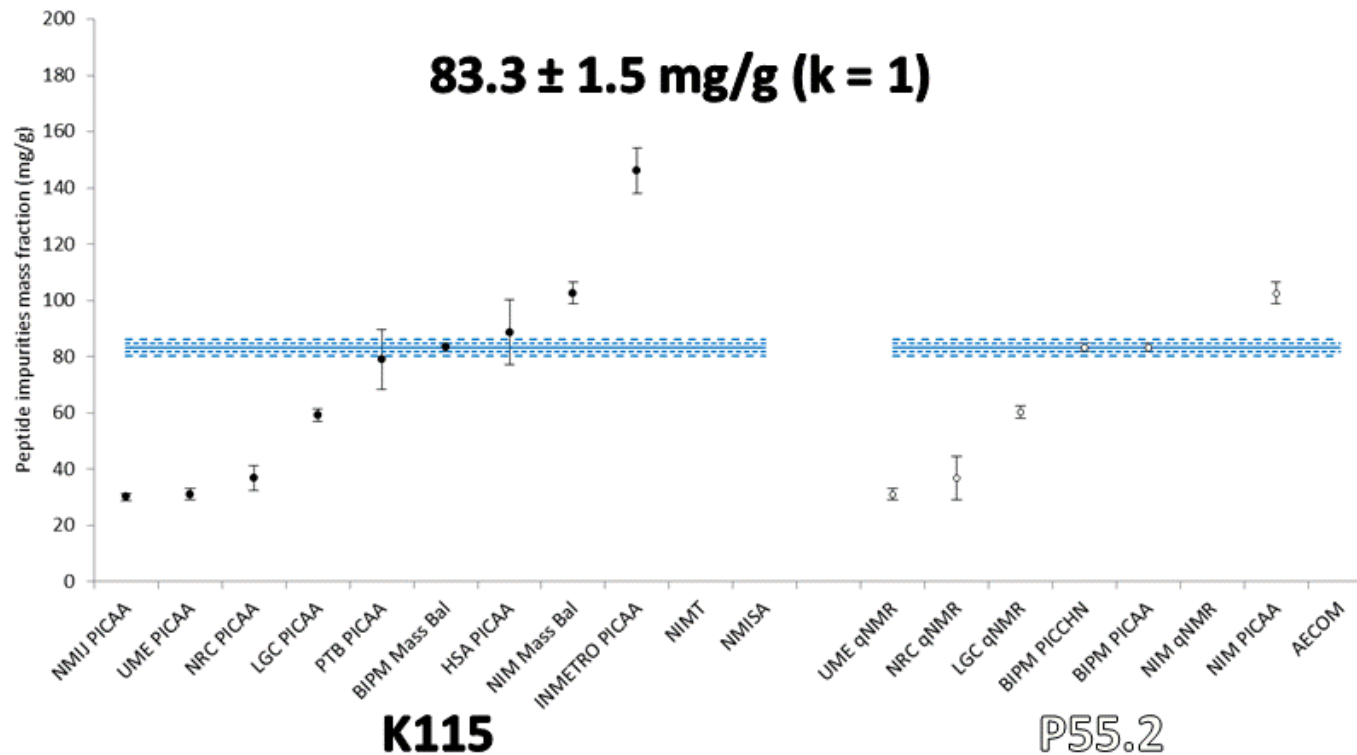
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I. Major Achievement

1. Accomplishment of K115/P55.2 study

- Purity determination of human C- peptide

CCQM-K115 and -P55.2 – KCRV_{PepImp}



1. Major Achievement

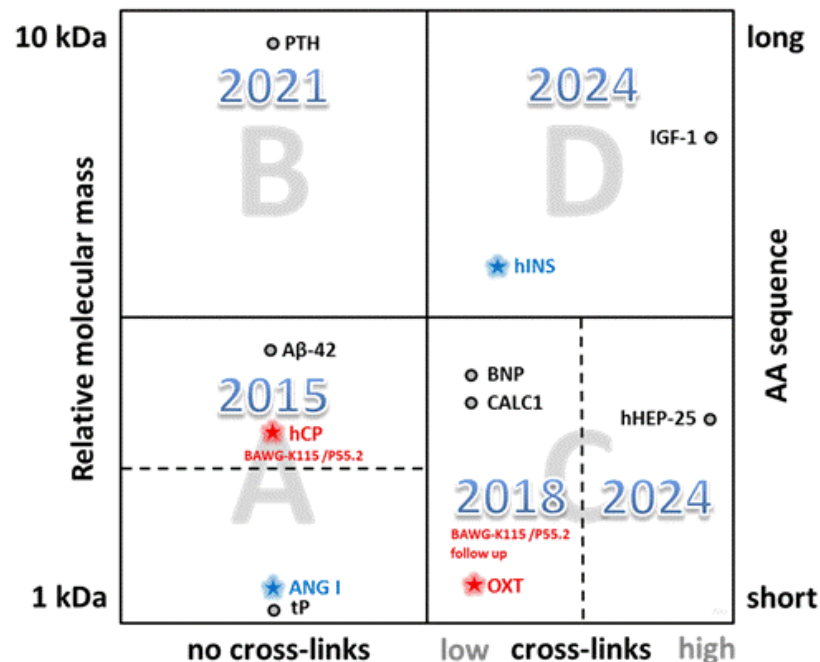
2. Two Focus Groups Launched

- Focus Group I: Measurement Traceability

CCQM-PAWG Focus Group I - Peptide/Protein Purity

Peptide	AAs	kDa	SSs
Tryptic Peptide Solution (tP)	~10	~1	0
Oxytocin (OXT)	9	1	1
Angiotensin I (ANG I)	10	1.2	0
Human Heparin-25 (hHEP-25)	25	2.8	4
Human C-Peptide (hCP)	31	3	0
Calcitonin Salmon (CALC1)	32	3.4	1
Brain Natriuretic Peptide (BNP)	32	3.5	1
Amyloid-Beta-42 (Aβ-42)	42	4.5	0
Human Insulin (hINS)	51	5.8	3
Insulin-like growth factor 1 (IGF-1)	70	7.6	3
Parathyroid hormone (PTH)	84	9.4	0

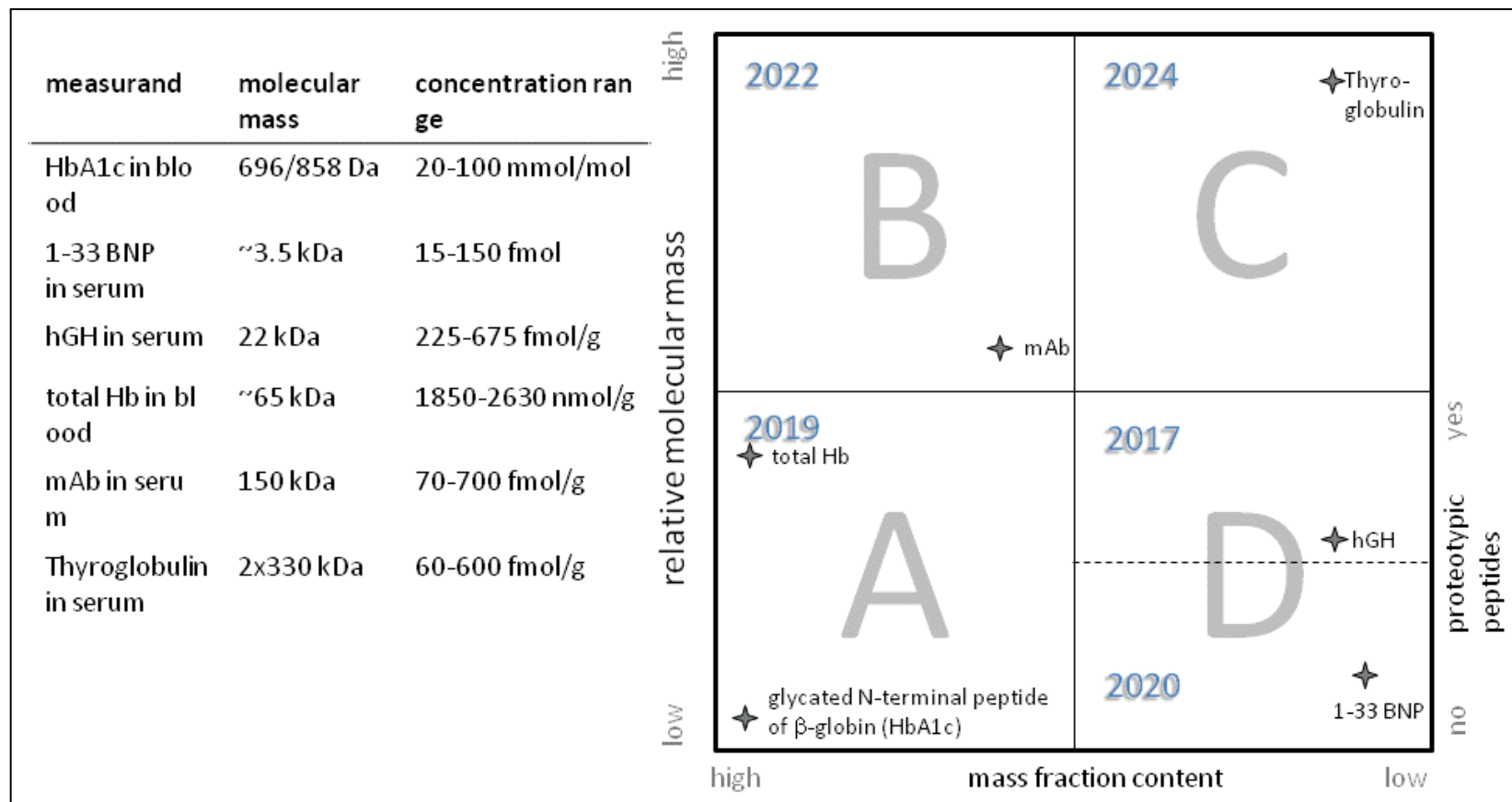
CCQM-K115
Peptide Purity Series



I. Major Achievement

2. Two Focus Groups Launched

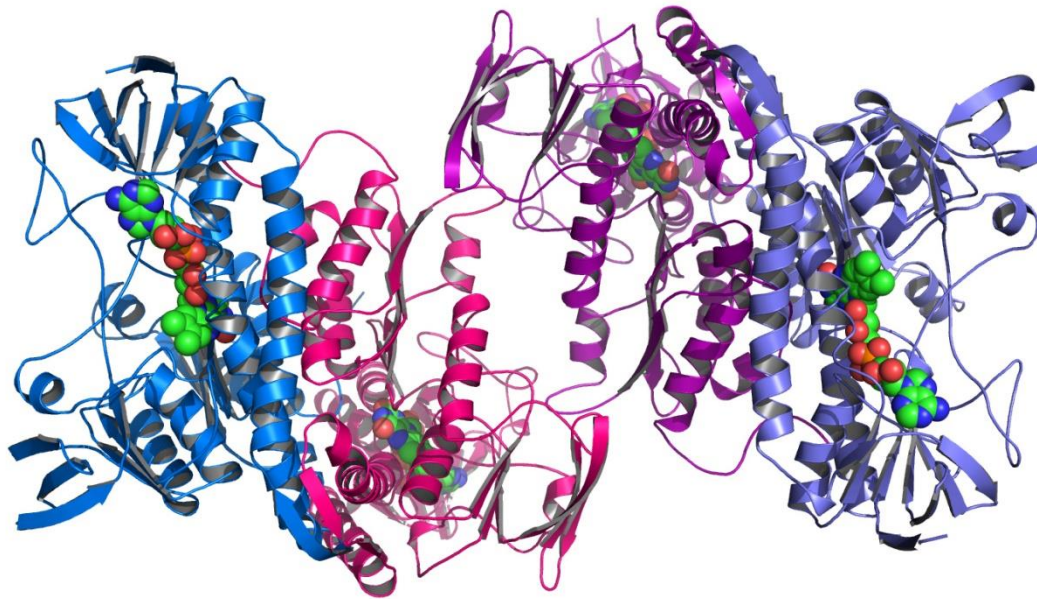
Focus Group 2: Measurement Capability



II. Major Challenges

❖ *Complexity in measurands*

- Enormous work and cost to establish traceability
- Relatively large uncertainty
- Large gaps between metrology and stakeholders

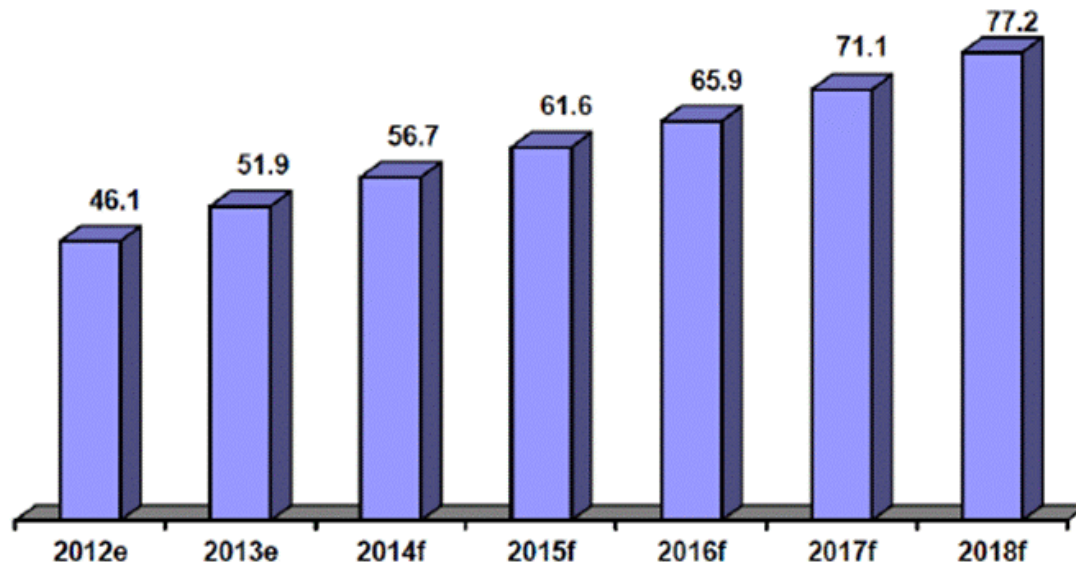


III. New in Strategy

- ❖ *The 3rd Focus Group (Metrology for Protein Biologics)?*
- To catch up high impact protein biologics industry

Promising growth of therapeutic antibodies

World-wide therapeutic antibodies markets (Billion US\$, 2012-2018)



出典 : Global Protein Therapeutics Market Outlook 2018 (RNCOS, January 2014)

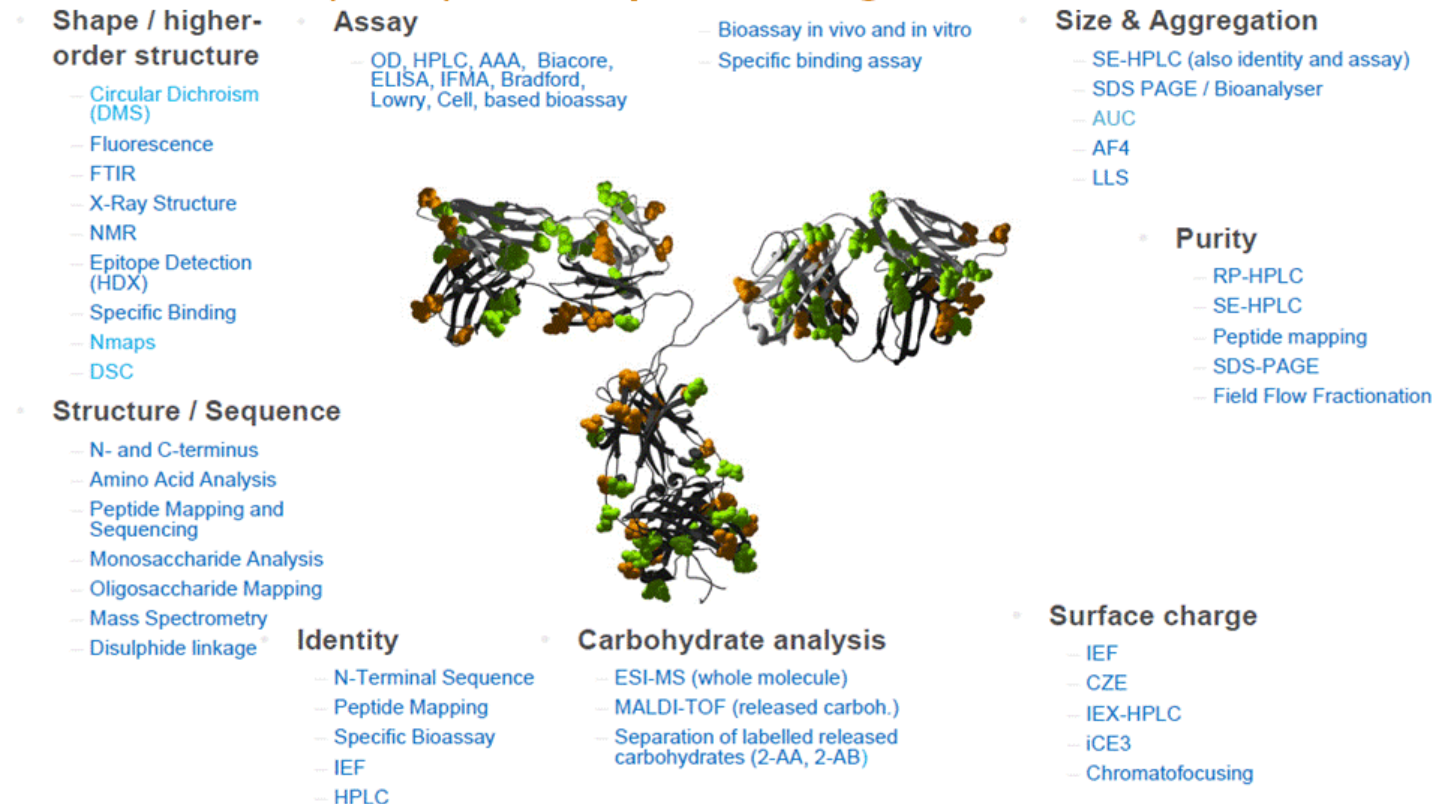
e:estimated, f:forecast

III. New in Strategy

- ❖ *The 3rd Focus Group (Metrology for Protein Biologics)?*
- A tremendous set of analytical methods applied

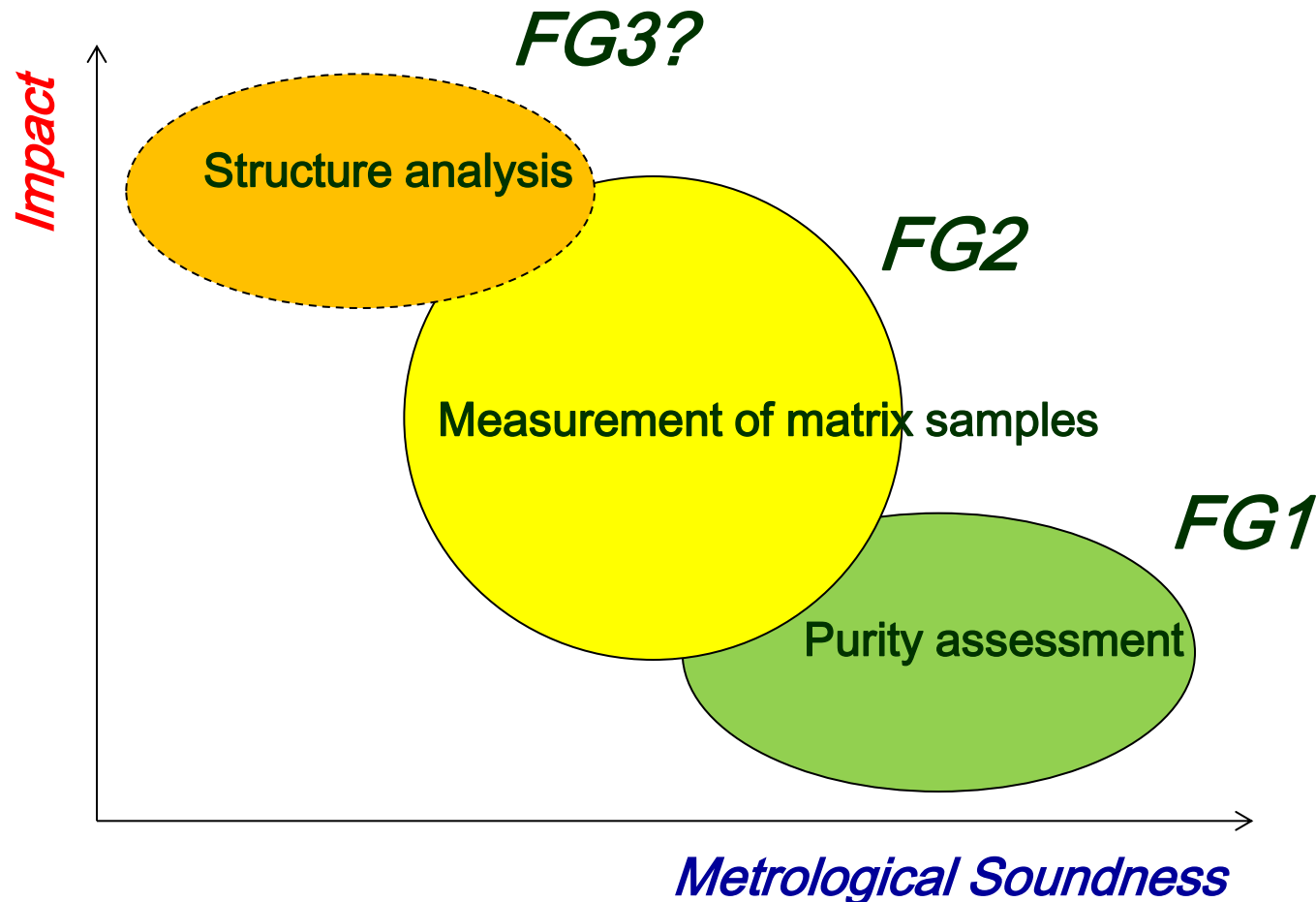
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Alternative version: Understanding the Critical Quality Attributes (CQA) of complex biological molecules



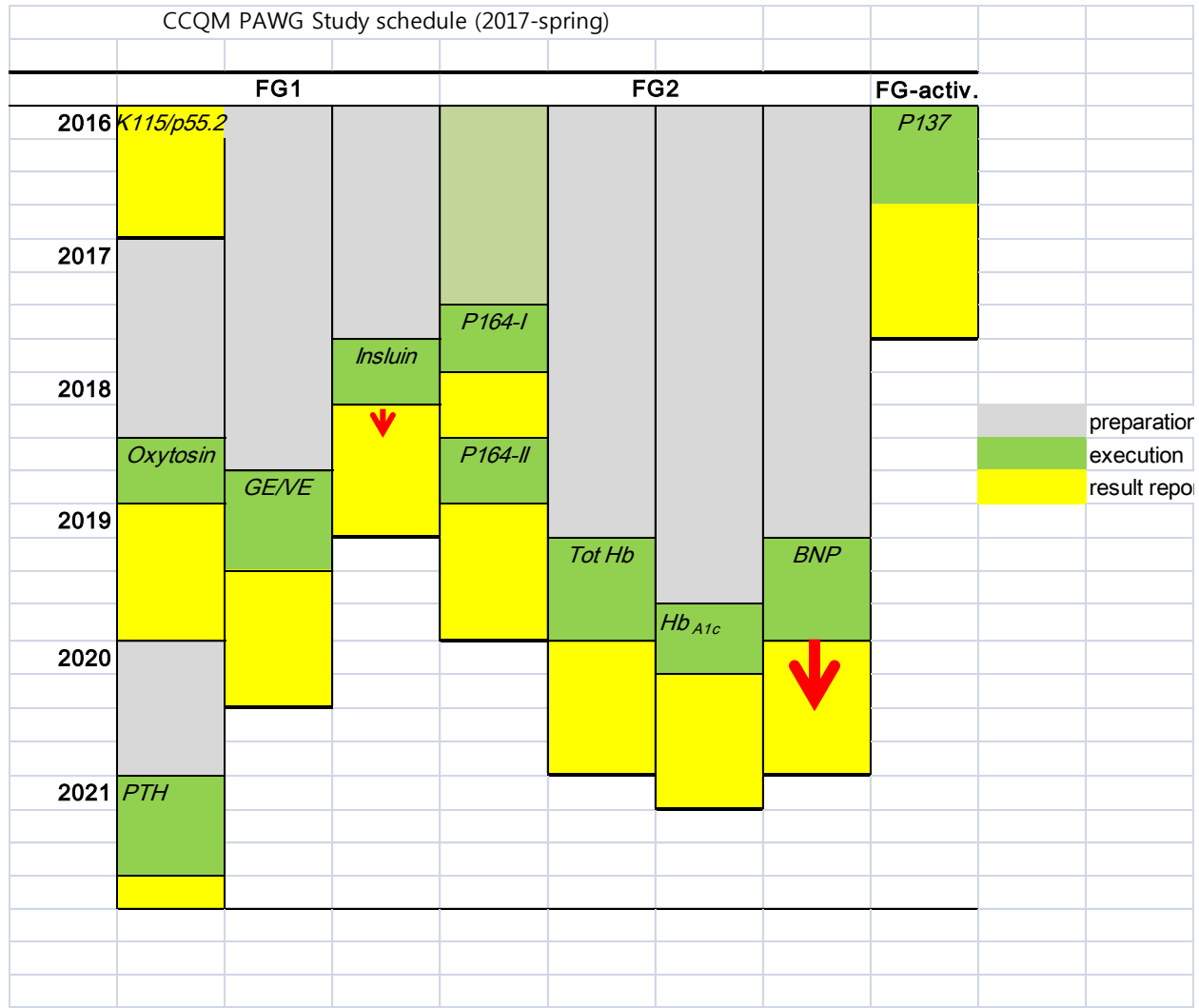
III. New in Strategy

- ❖ *The 3rd Focus Group (Metrology for Protein Biologics)?*
 - To catch up high impact protein biologics industry



IV. Planned comparisons

❖ *One comparison for each focus group a year*



Thank you!

