

# USA Clinical study result



## ▶ Clinical trial period

- 2016.05.02 – 2016.07.31 (3months)

## ▶ Clinical trial Location

- Integrative Health Technologies, Texas, U.S.A.

## ▶ Purpose of the study

1. To compare measurement data with competitors(C company, H company), and DEXA(gold standard for Body composition analysis)

2. Perform separate 2 clinical trials to improve algorithm accuracy

(1<sup>st</sup> clinical trial – 75 subjects / 2<sup>nd</sup> clinical trial -75 subjects / additional 11 subjects)

1<sup>st</sup> clinical trial is performed with previous equation of SELVAS BCA.

2<sup>nd</sup> clinical trial is performed with upgraded equation applied 1<sup>st</sup> session's measurement result.

11 subjects are additionally measured for various body type analysis and added to 2<sup>nd</sup> clinical trial. So total subjects of 2<sup>nd</sup> clinical trial is modified to 86.

# ▶ Data analysis

- Statistical analysis is performed on age, height, weight and BMI etc...
- 1<sup>st</sup> clinical trial – 64 subjects are statistically analyzed among 75 enrolled subjects.
- 2<sup>nd</sup> clinical trial – 79 subjects are statistically analyzed among 86 enrolled subjects.

<1st clinical trial>			<2nd clinical trial>		
Variables	Male(N=25)	Female(N=39)	Variables	Male(N=39)	Female(N=40)
	Mean±SD	Mean±SD		Mean±SD	Mean±SD
AGE(years)	41.5±17.3	50.5±14.1	AGE	31.1±14.7	32.3±15.4
Height (cm)	175.3±6.4	161.6±7.4	Height (cm)	174.8±7.9	162.5±6.9
Weight (kg)	79.2±16.9	71.1±14.7	Weight (kg)	78.5±13.5	66.2±12
Waist	89.6±13.9	85.1±12.9	Waist	86.9±12.2	80±11.7
BMI(kg/cm2)	25.7±5.1	27.3±5.8	BMI(kg/cm2)	25.7±3.8	25.2±5.2
Visceral fat area_I company(cm2)	80.6±50	103.3±44.1	Visceral fat area_I company(cm2)	0±46.2	86.8±43.3
Visceral fat area_X970(cm2)	100±48.6	106.3±59.9	Visceral fat area_X970(cm2)	113.1±78.2	155.8±113.8
Percent body fat_DXA(%)	23.9±9.7	38.9±10.9	Percent body fat_DXA(%)	23.4±9.3	37.7±9.8
Percent body fat_I company(%)	23.2±10	36.7±12.4	Percent body fat_I company(%)	20.9±9.9	32.7±11.6
Percent body fat_T company(%)	20.1±6.6	33.2±9.1	Percent body fat_T company(%)	19.4±6.1	30.5±7.9
Percent body fat_X970(%)	21.5±6.5	33.5±9	Percent body fat_X970(%)	23.9±8.7	38±9
Body fat mass_DXA(kg)	19.8±11.7	29±12.6	Body fat mass_DXA(kg)	19.1±10.2	25.5±10.4
Body fat mass_I company(kg)	19.7±12.6	27.5±13.6	Body fat mass_I company(kg)	17.2±10.7	22.7±11.8
Body fat mass_T company(kg)	16.8±9.3	24.6±10.7	Body fat mass_T company(kg)	12.7±0	12.7±0
Body fat mass_X970(kg)	17.8±9	40.7±5.3	Body fat mass_X970(kg)	19.5±9.9	26±10.3
Lean body mass_DXA(kg)	58.3±8.9	40.7±5.3	Lean body mass_DXA(kg)	59.2±7.8	39.9±4.4
Lean body mass_I company(kg)	59.5±8.3	43.5±5.7	Lean body mass_I company(kg)	61.3±8.4	43.4±4.6
Lean body mass_T company(kg)	62.2±8.9	46.5±6.4	Lean body mass_T company(kg)	62.7±7.8	45.2±4.4
Lean body mass_X970(kg)	61.1±9.3	46.3±7.3	Lean body mass_X970(kg)	58.9±7.6	40.1±4.3

## I. Exception reason -

### 11 subjects from 1<sup>st</sup> clinical trial

- No. 1,2,3,13,25, 35 – Weight input error
- No. 47, 58, 60, 67, 99998 - Height input error

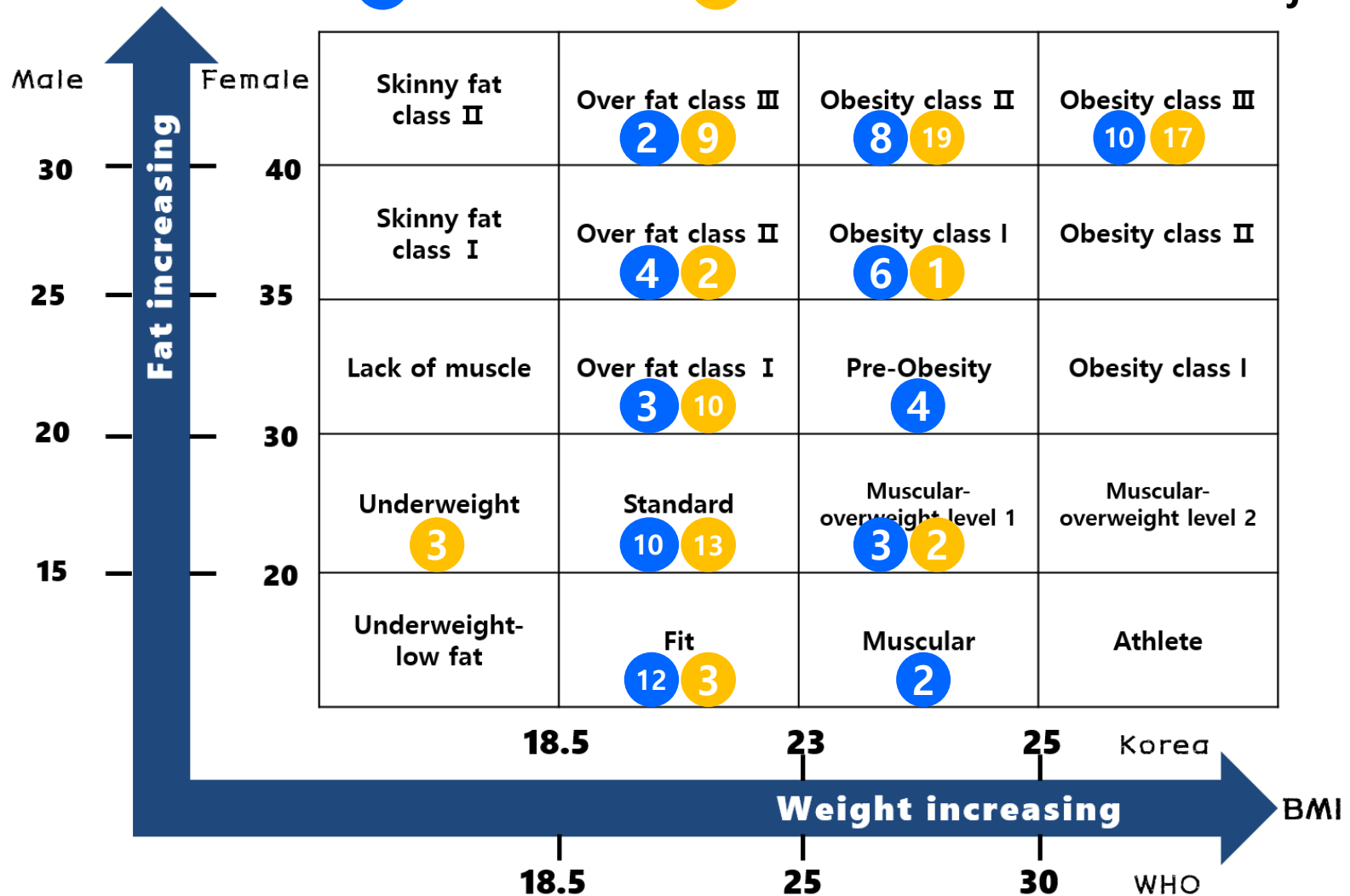
## II. Exception reason

### 7 subjects from 2<sup>nd</sup> clinical trial

- No. 92, 99, 103, 111, 115, 132 – Abnormal impedance range of SELVAs data
- No. 112 – Abnormal PBF range of C company data (ex. DEXA PBF-29.8%, C company PBF-3%)

## ► Distribution of subject

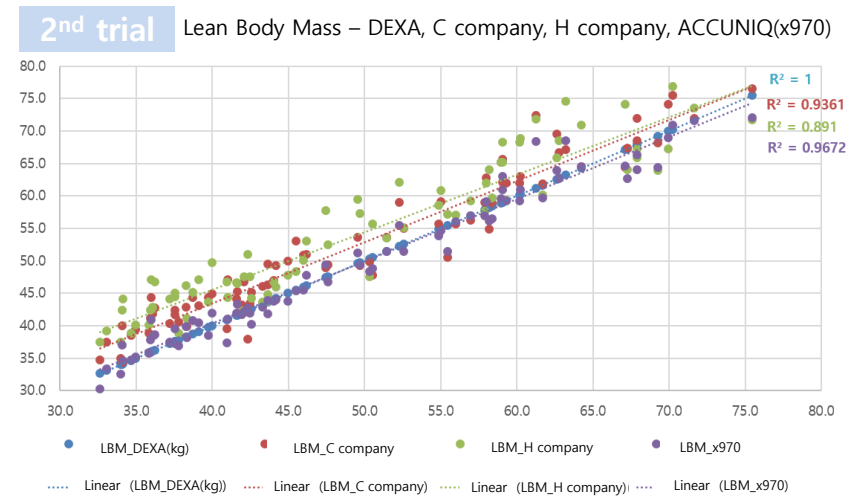
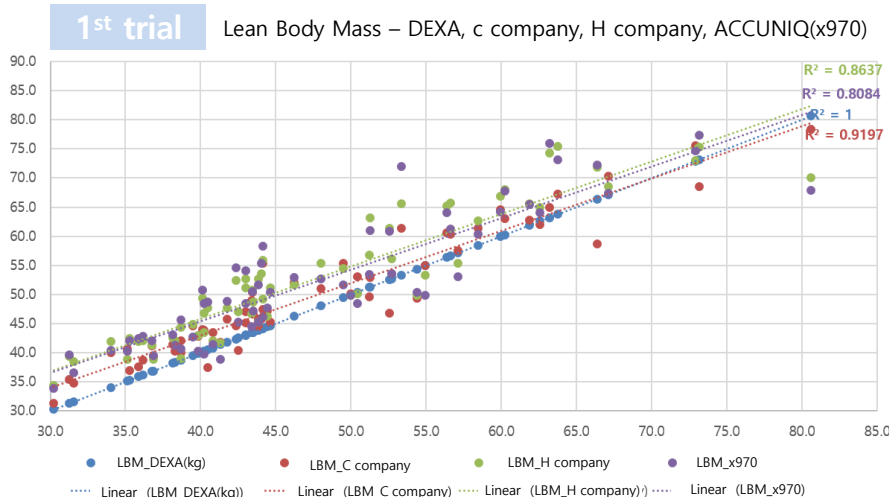
Percent Body Fat ● Male : 64 + ● Female : 79 = total 143 subjects



# Lean Body Mass comparison

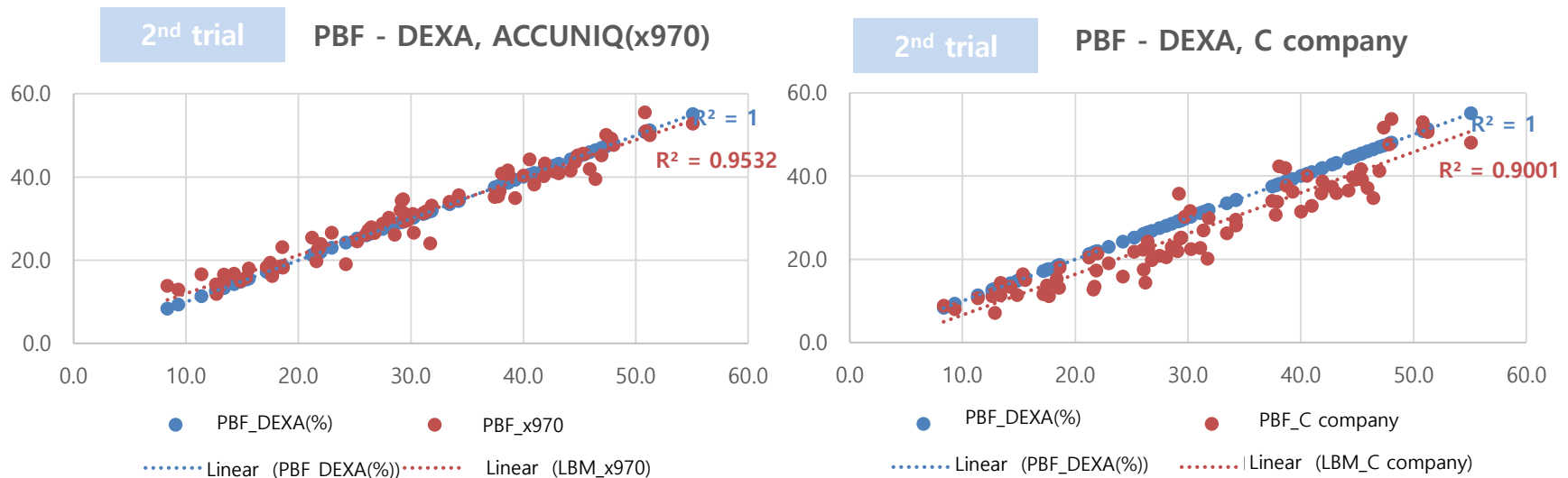
- These are LBM comparison measured by DEXA, ACCUNIQ(Jawon X Scan PLUS 970), C company, and H company.
- Determination of coefficient( $R^2$ ) of DEXA is 1, and accuracy of each BCA unit is higher if  $R^2$  value is close to 1.
- The accuracy of ACCUNIQ(Jawon X Scan PLUS 970) is higher than competitors in 2<sup>nd</sup> clinical trial if you see below table of LBM  $R^2$ .

Lean Body Mass $R^2$ value	No.	DXA	C company	H company	ACCUNIQ
	1 <sup>st</sup> clinical trial	1	0.9197	0.8637	0.8084
	2 <sup>nd</sup> clinical trial	1	0.9361	0.891	0.9672



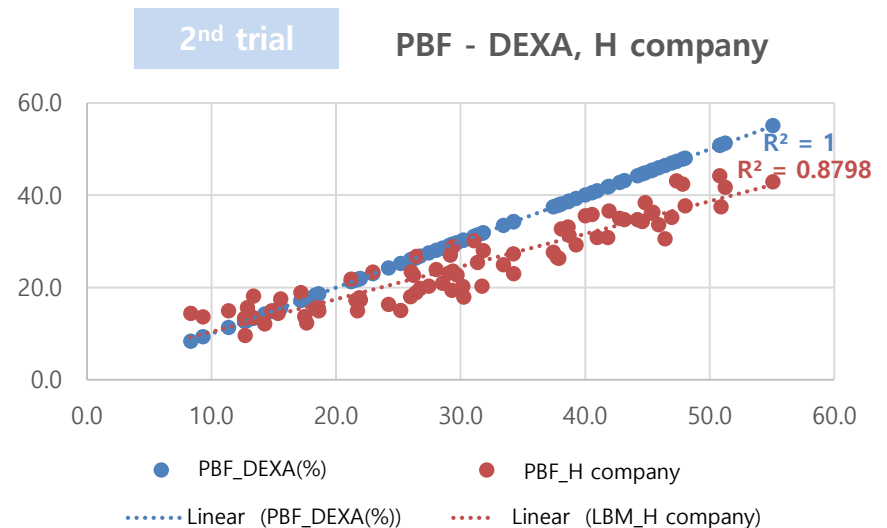
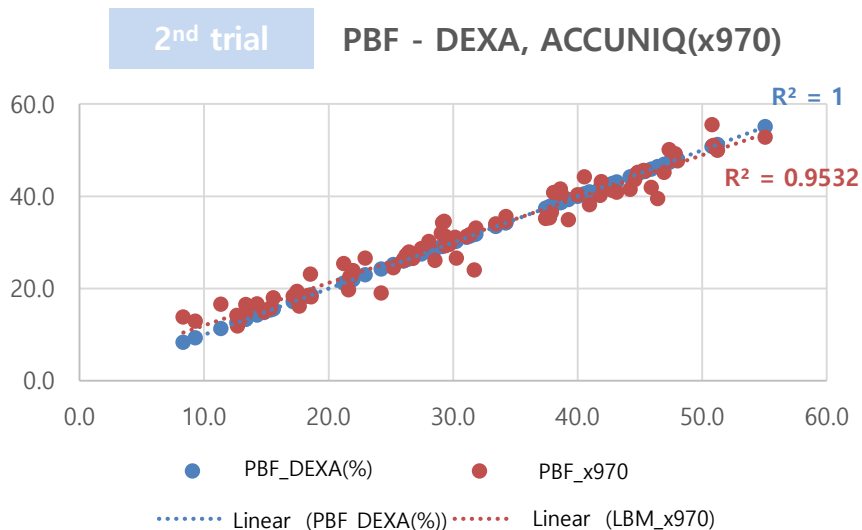
# ▶ Percent Body Fat Comparison(C company)

- These are PBF comparison measured by DEXA, ACCUNIQ (Jawon X Scan PLUS 970), and C company.
- The accuracy of ACCUNIQ(Jawon X Scan PLUS 970) is higher than C company if you see PBF R<sup>2</sup> values of ACCUNIQ(R<sup>2</sup>=0.9532) and C company(R<sup>2</sup>=0.9001)



# ▶ Percent Body Fat Comparison(H company)

- These are PBF comparison measured by DEXA, ACCUNIQ(Jawon X Scan PLUS 970), and H company.
- The accuracy of ACCUNIQ(Jawon X Scan PLUS 970) is higher than H company if you see PBF R<sup>2</sup> values of ACCUNIQ(R<sup>2</sup>=0.9532) and H company(R<sup>2</sup> =0.8798)



## ► Statistical analysis

- These are statistical analysis result of BCA and DEXA measurement .
- P-value of competitor is less than 0.05 by paired t-test, so the result of C company and H company is significantly different with DEXA. However, ACCUNIQ(JAWON X Scan PLUS 970) shows positive correlation with DEXA.
- As a result of that, we can say ACCUNIQ(JAWON X Scan PLUS 970)'s measurement result is same with DEXA in 2<sup>nd</sup> clinical trial.
- Mean differences of percent body fat between DEXA and C company is  $3.8 \pm 0.4$ . DEXA and H company is  $5.6 \pm 3$ . DEXA and ACCUNIQ is  $-0.4 \pm 0.7$ .
- ACCUNIQ shows minimum mean differences with DEXA compare to the others.

Variables	Body composition								
	Percent body fat(%)			Body fat mass(kg)			Lean body mass(kg)		
	Mean±SD	P-value	Explanation	Mean±SD	P-value	Explanation	Mean±SD	P-value	Explanation
DEXA – C company	$3.8 \pm 0.4$	< 0.05	DEXA PBF ≠ C company PBF	$2.3 \pm 0.8$	< 0.05	DEXA BFM ≠ C company BFM	$-2.9 \pm 0.3$	< 0.05	DEXA LBM ≠ C company LBM
DEXA – H company	$5.6 \pm 3$	< 0.05	DEXA PBF ≠ H company PBF	$9.7 \pm 10.9$	< 0.05	DEXA BFM ≠ H company BFM	$-4.5 \pm 0.7$	< 0.05	DEXA LBM ≠ H company LBM
DEXA - ACCUNIQ	$-0.4 \pm 0.7$	0.17	DEXA PBF = ACCUNIQ PBF	$-0.4 \pm 0.2$	0.06	DEXA BFM = ACCUNIQ BFM	$0 \pm 0.3$	0.99	DEXA LBM = ACCUNIQ LBM