How to ensure the reliability of PET data in clinical trials: the FIL experience

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1. Expert Panel Review

Multiple image interpretation

3. Scanner Equalization

Varying makers/models of imaging equipment

2. Procedure Harmonization

Varying image/acquisition protocols
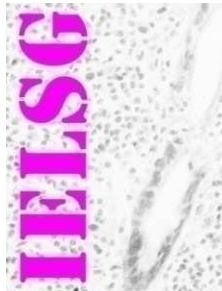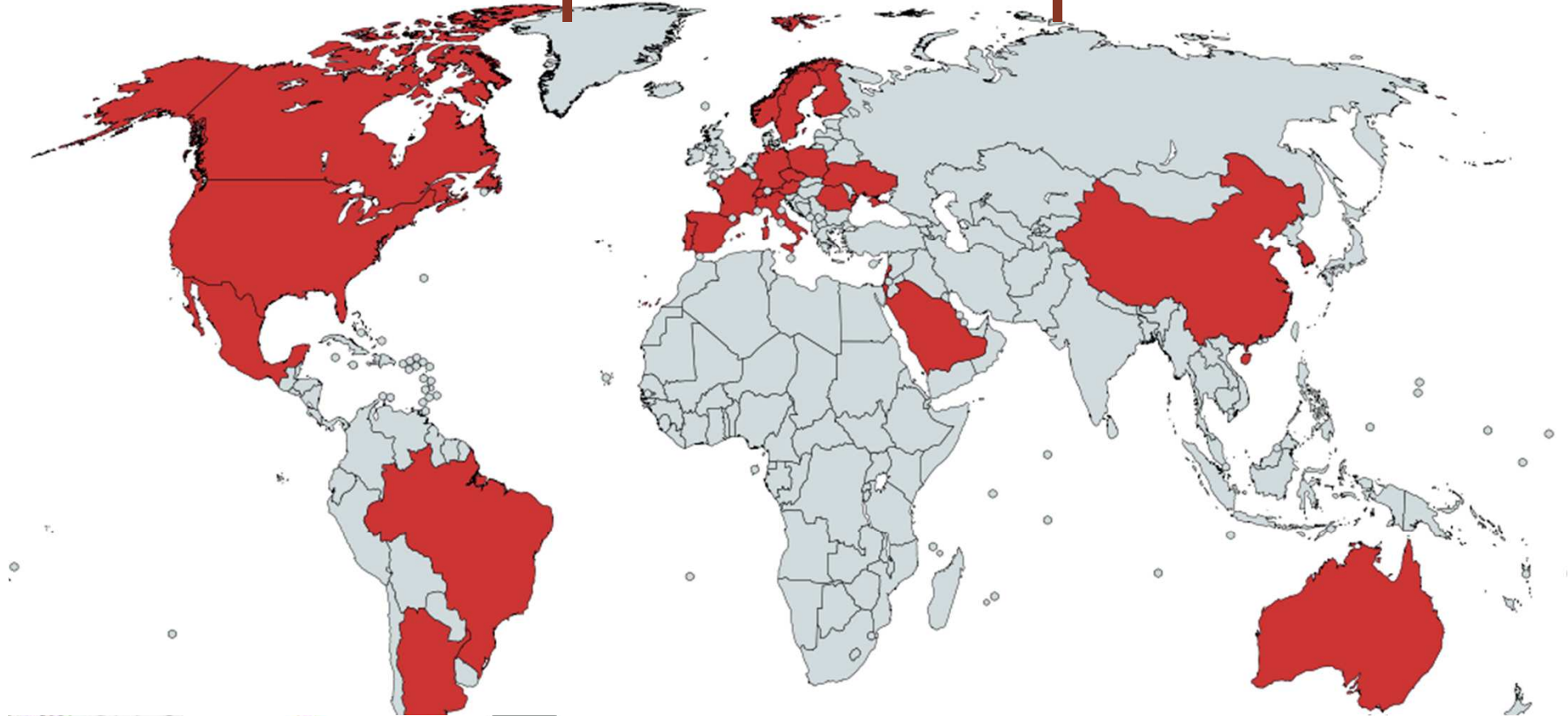
CUNEO PET CORELAB

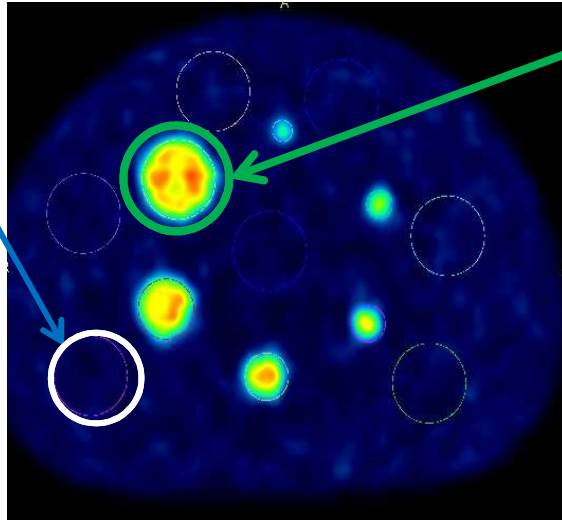**230** CENTERS | **26** COUNTRIES | **4** WHOLE NATION
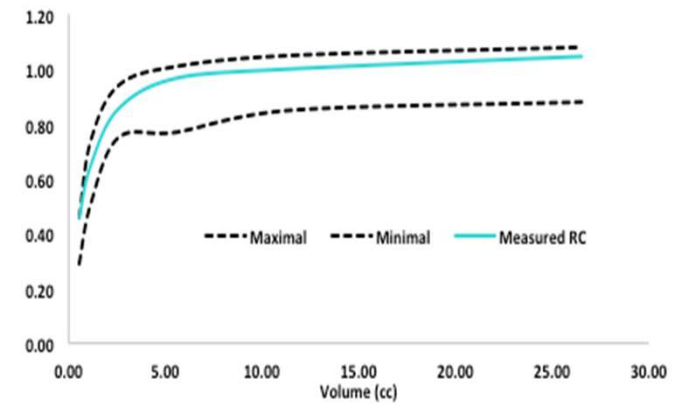
SCANNER EQUALIZATION

Background Activity
Concentration
(BAC)

Sphere to Background
Ratio in the largest spheres
(SBR)

Scanner
Calibration

Reconstruction
algorithm optimization

INTER SCANNER VARIABILITY
ISV= 95% C.I.

CTQ FOR QUALITATIVE SCALE
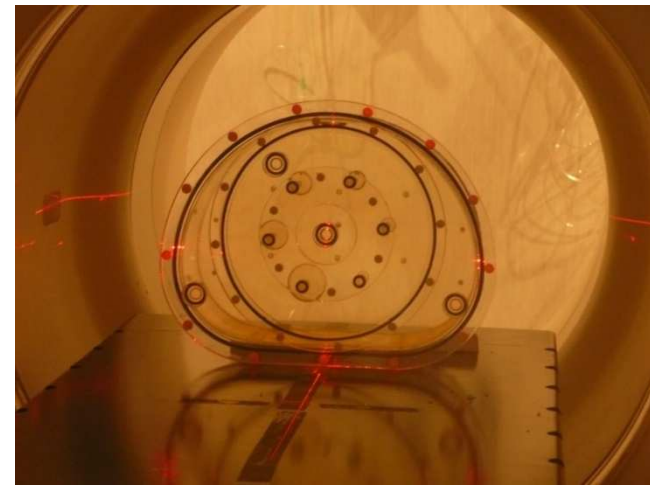
in collaboration with AIFM
and AIMN since 2007

^{18}F Phantoms done by local expert

Limits for CTQ:
◦ BAC±10%
◦ RC Curve between EANM Guidelines

Free of partecipation

All PET sites participating at FIL trials

Rozzano, BS, BG, MB, MI-int (2), MI-Niguarda, MI-pol, Mi-Sanpaolo, MI-hsr (2+1), MI-ieo, PV, VA

BZ, TN

PD, Mestre, VR, TV, Castelfranco, VI

Aviano, UD

75 PET sites
85 PET scanner

RE, PR (2), MO, BO (2), Meldola, CE

AL, CN, NO, Candiolo,TO-CdS, TO-Irmet (2)

AN, MC, AP

GE

PE

PI, AR, FI, PO, Carrara

CB

BA, BR, , LE, S.G.Rotondo, FG

PG, Terni, Foligno

RM-tv (2), RM-ifo, LT, RM-Gem
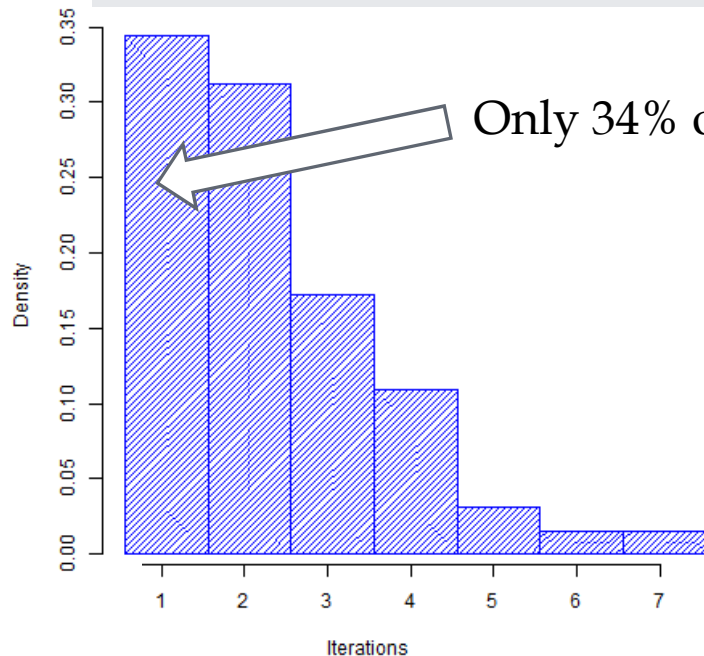
SA, NA-Pa, NA-SDN (3), AV,Na-Fed II

Rionero, PZ

CA-bi, CA-bu

CS,CZ

CT,CT-gn, ME, PA, PA-Mad(2), Cefalù, ME-Papardo

CTQ FOR QUALITATIVE SCALE

FREQUENCY OF ITERATIONS

Only 34% of PET/CT sites qualified at first iteration!

Problems in qualification:
- No trained personnel (5 sites)
- Lack of phantoms (12 sites)
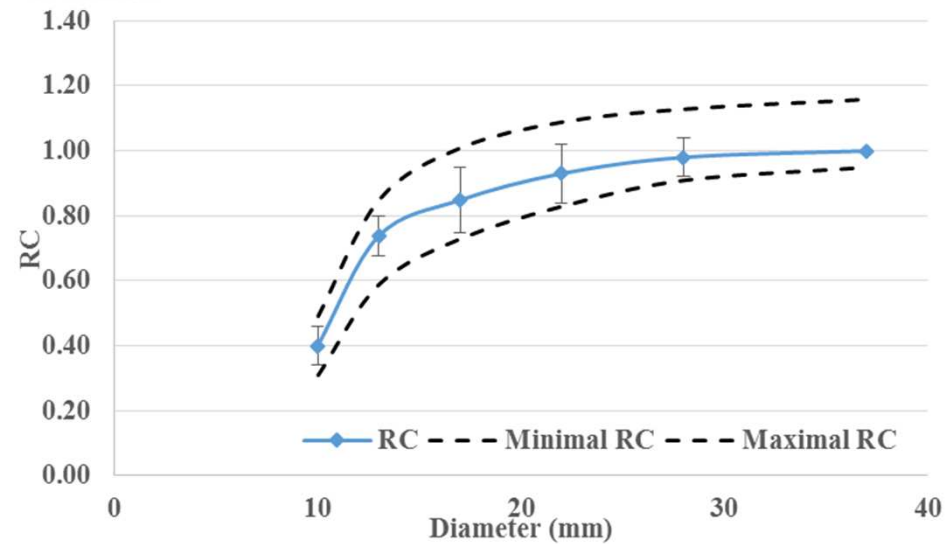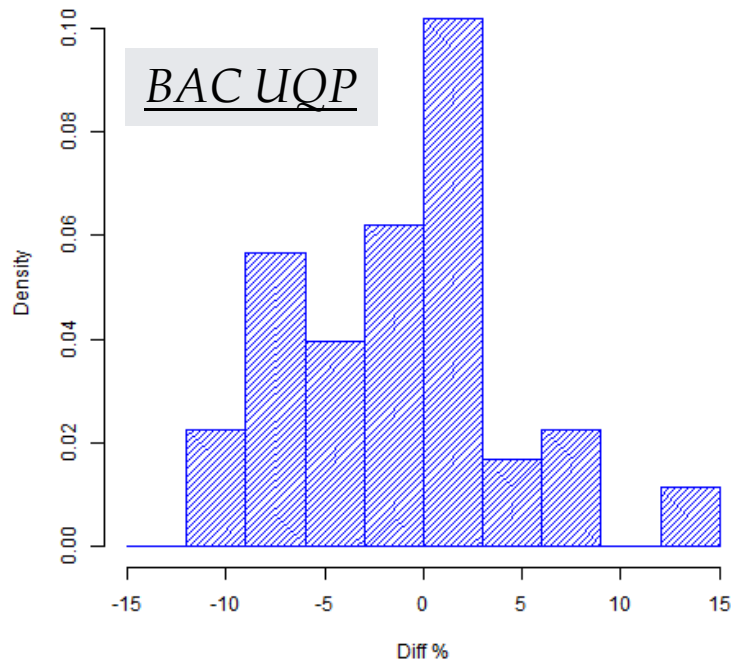
CTQ FOR QUALITATIVE SCALE

BAC in UQP

95% CI (-11.9 to +9.3%)
ISV: 21.2%

SBR in IQ

95% CI (-18.3% to 32.3%)
ISV: 50.6%

BAC UQP
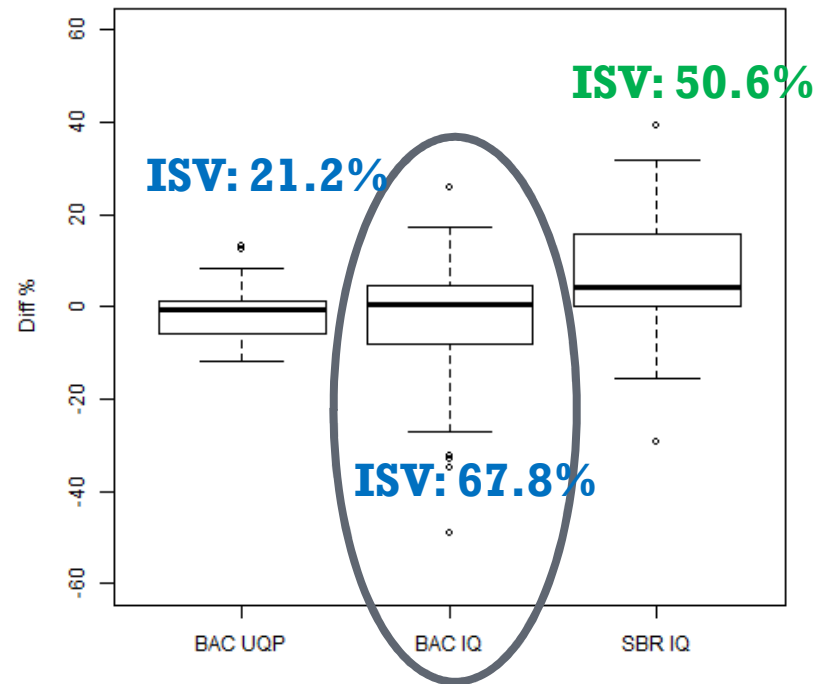
CTQ FOR QUANTITATIVE SCALE

BAC in IQ

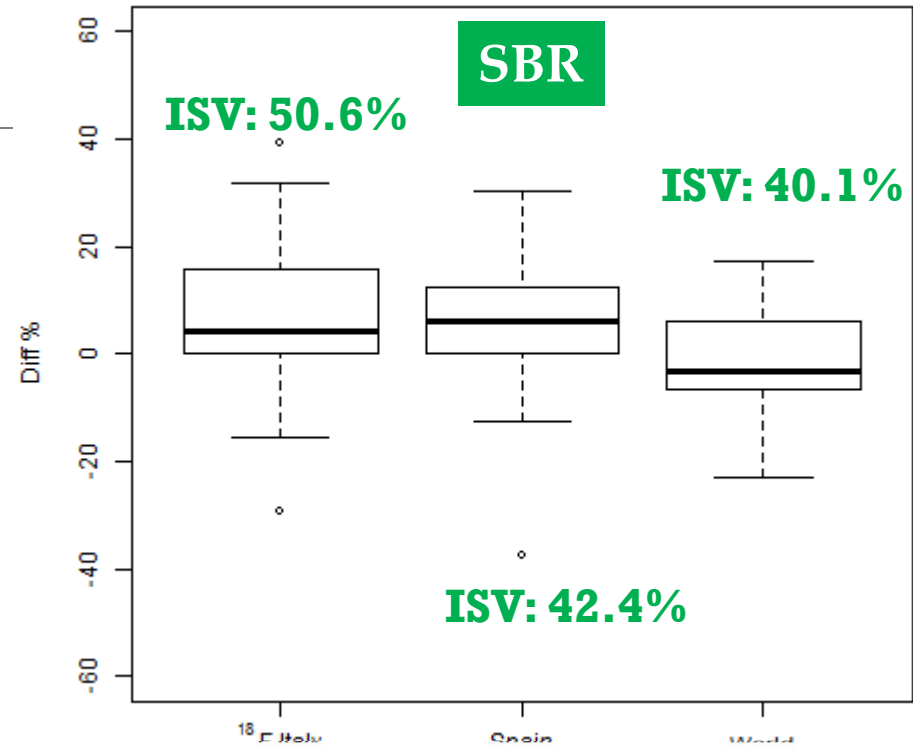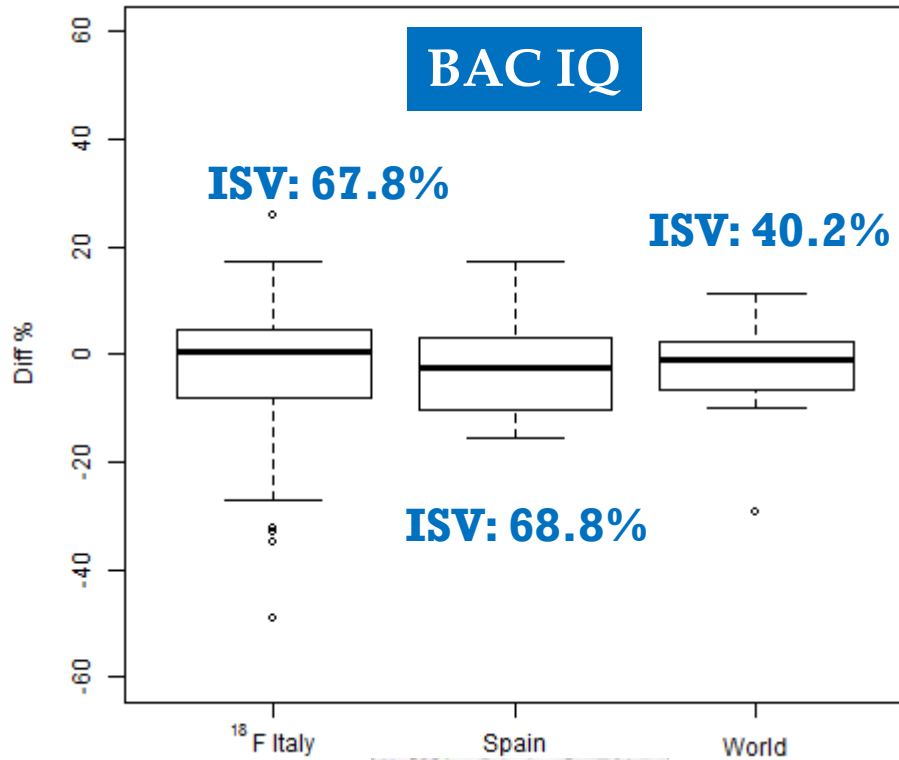(the one not used for absolute calibration)

95% CI (-38.1 to +29.7%)

ISV: 67.8%

INTERNATIONAL EXPERIENCE

CTQ FOR QUANTITATIVE SCALE

NEMA PET Phantom with 8 hot spheres
- Radionuclide: Ge-68
- Half-life: 270.8 days

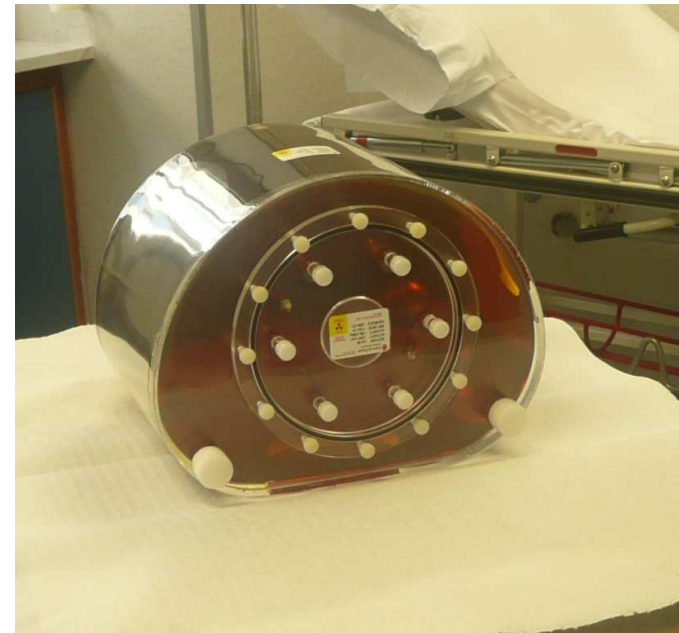^{68}Ge Phantoms

Limits for CTQ:
◦ BAC±10%
◦ RC Curve between EANM Guidelines

Free of participation
grant RF-CROB-2008-1146343 Ministero della Salute

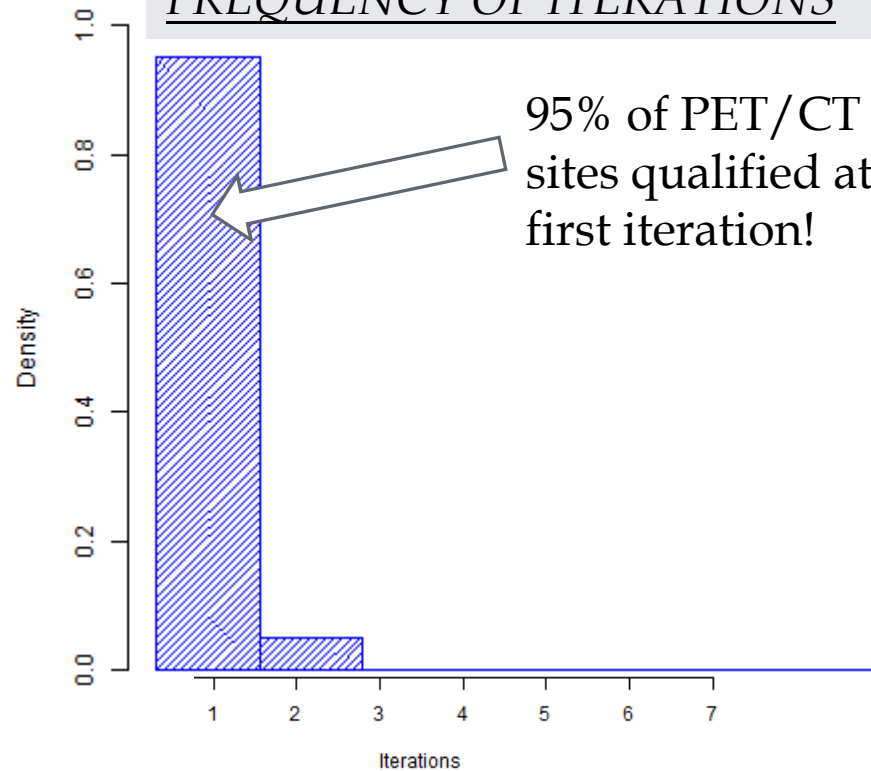MB, MI-hsr (1+1)

Castelfranco

UD

CN, NO

RE, MO

PO

PE

PG, Terni, Foligno

RM-tv

Ge^{68}
phantom
Both

NA-SDN (3)

PA-Mad(2)
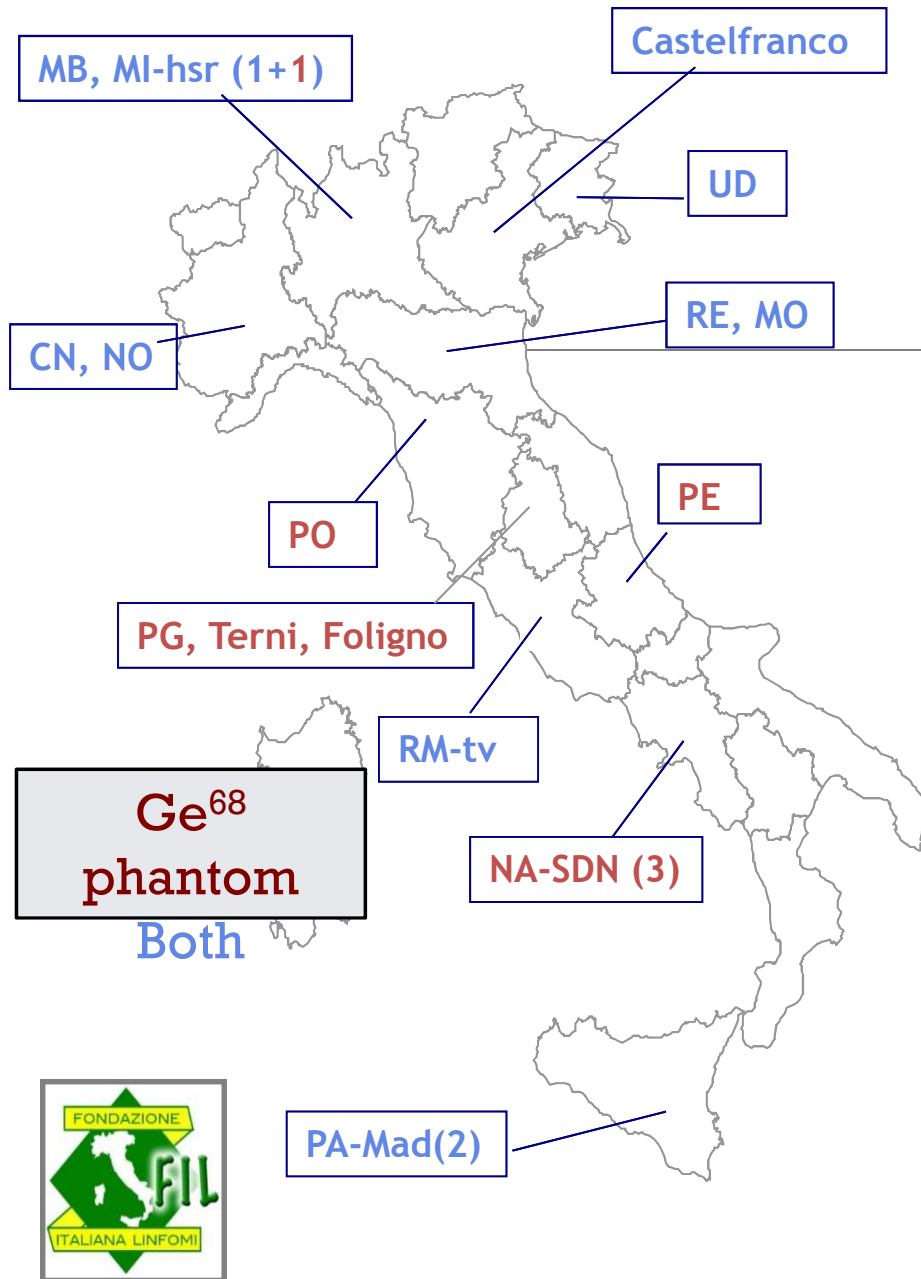
20 PET scanner qualified

FREQUENCY OF ITERATIONS

95% of PET/CT sites qualified at first iteration!

CTQ FOR QUANTITATIVE SCALE

REDUCTION OF A FACTOR 3

ISV: 24.4%   ISV: 19.8%

ISV: 67.8%   ISV: 50.6%

^{18}F BAC ^{68}Ge BAC ^{18}F SBR ^{68}Ge SBR
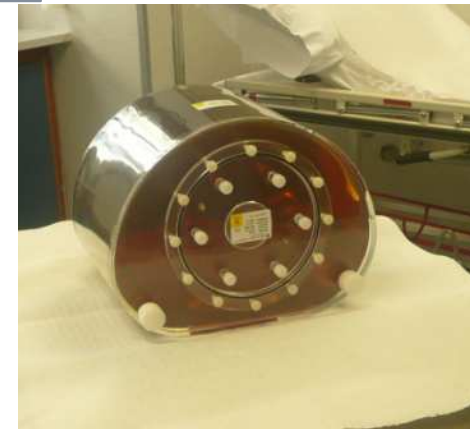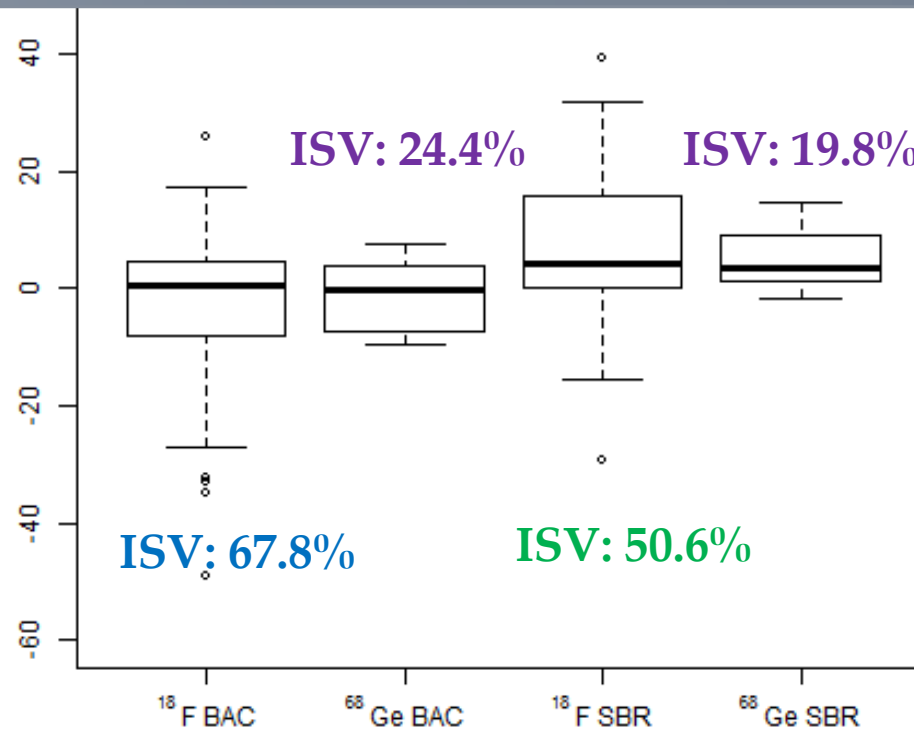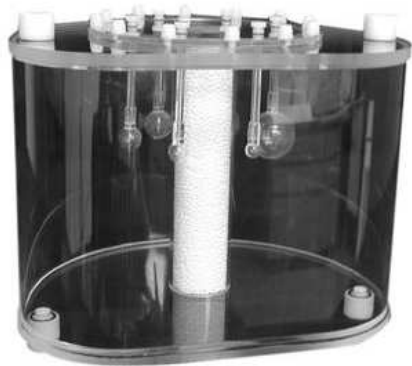
Original paper

The ^{68}Ge phantom-based FDG-PET site qualification program for clinical trials adopted by FIL (Italian Foundation on Lymphoma)

Stephane Chauvie [a,*], Fabrizio Bergesio [a], Federica Fioroni [b], Marco Brambilla [c], Alberto Biggi [a], Annibale Versari [h], Luca Guerra [d], Giovanni Storto [e], Pellegrino Musto [e], Stefano Luminari [f], Maria G. Cabras [a], Monica Balzarotti [h], Luigi Rigacci [i], Maurizio Martelli [j], Umberto Vitolo [k], Massimo Federico [f], Andrea Gallamini [l]

CTQ FOR ABSOLUTE QUANTIFICATION

FIL - AQQ

UBER Phantom
- ✓ cylindrical
- ✓ 8 hot spheres
- ✓ 1 insert to simulate lesion

Eckert & Ziegler
Contributing to saving lives

Lesion Detectability performance of new scanners

Cross-Calibration

Noise evaluation

Optimization of reconstruction algorithm

Choose of best segmentation algorithm

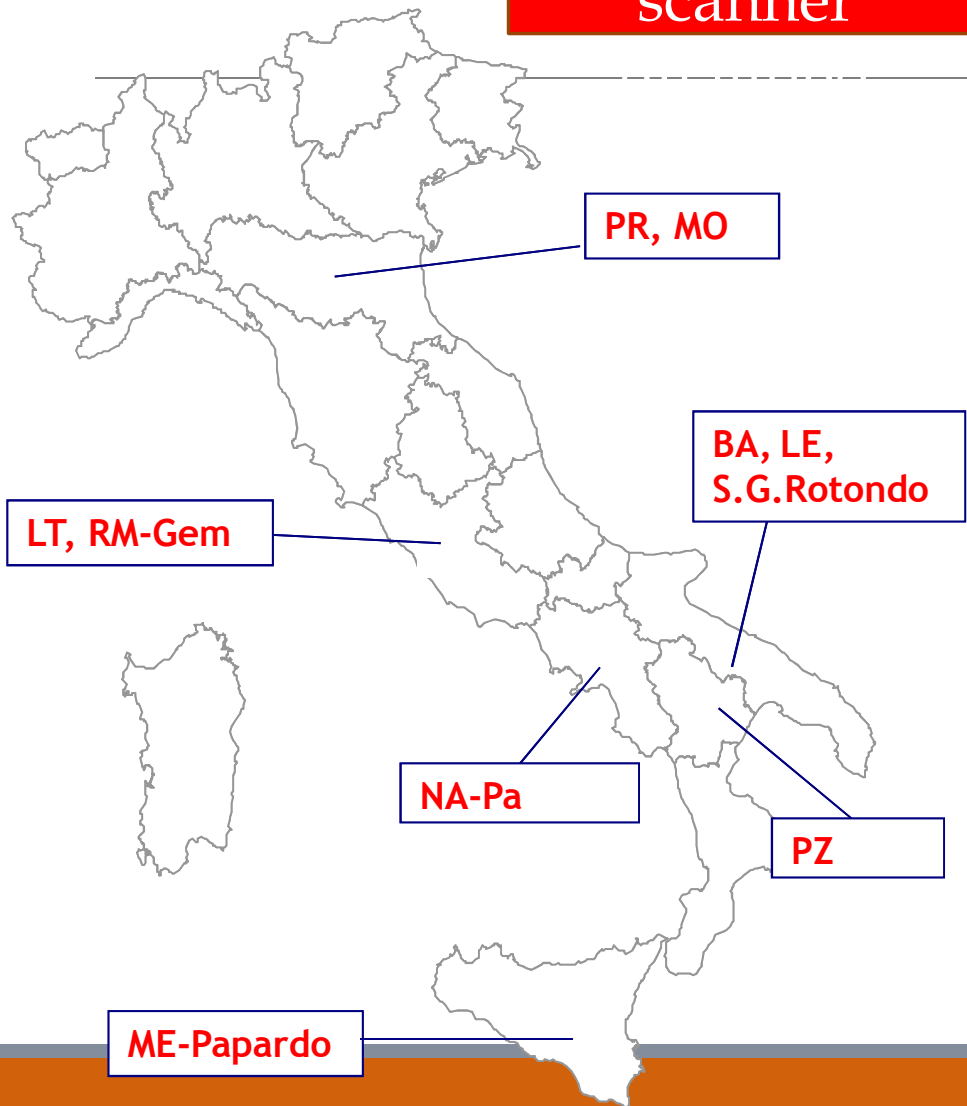Uber phantom was acquired in Lugano Hospital

CTQ FOR ABSOLUTE QUANTIFICATION

20 PET scanner

PR, MO

BA, LE, S.G.Rotondo

LT, RM-Gem

NA-Pa

PZ

ME-Papardo

FREQUENCY OF ITERATIONS

Number of Iterations

90% of PET/CT sites qualified at first iteration!
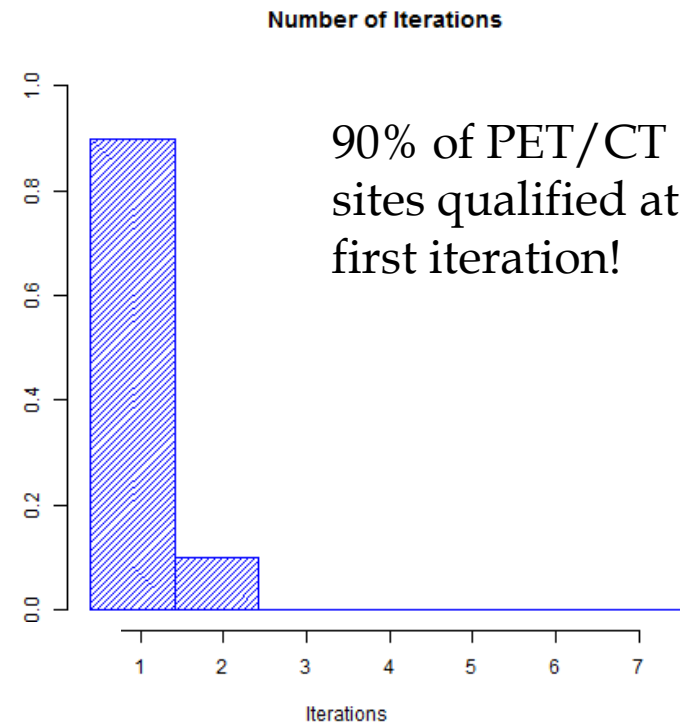
CTQ FOR ABSOLUTE QUANTIFICATION

64 scanner

10 scanner

ISV: 20.3%

ISV: 26.5%

ISV: 67.8%

ISV: 50.6%
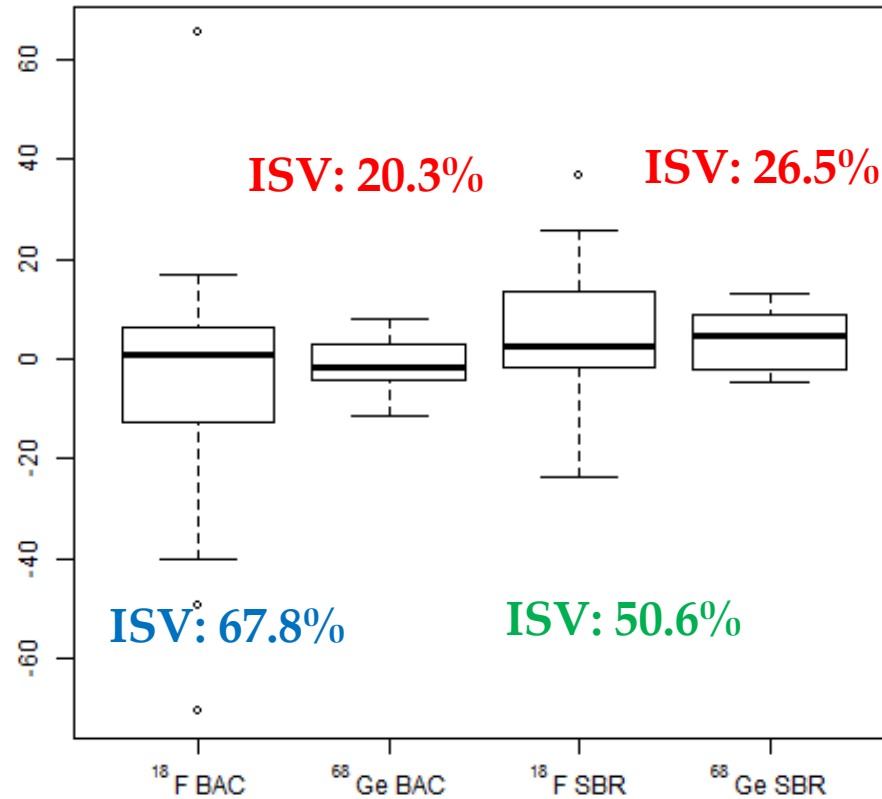
^{18}F BAC ^{68}Ge BAC ^{18}F SBR ^{68}Ge SBR

Analogous reduction

CONCLUSIONS

^{18}**F** CTQ

- ✓ useful for qualitative scale, **not** for quantitative scale

- ✓ not simple to do (need experience and phantom)

^{68}**Ge** CTQ

- ✓ useful for quantitative scale

- ✓ no problem in preparation and acquisition

- ✓ possibility to introduce new features (optimization of reconstruction algorithm)

UBER CTQ

- ✓ cross calibration

- ✓ evaluation of new reconstruction algorithm

- ✓ reduction of limit and introduction of new request for CTQ

75 PET sites
84 PET scanner

Rozzano, BS,BG, MB, MI-int (2), MI-Niguarda, MI-pol, Mi-Sanpaolo, MI-hsr (2+1), MI-ieo, PV, VA

BZ, TN

PD, Mestre, VR, TV, Castelfranco, VI

Aviano, UD

RE, PR, MO, BO (2), Meldola, CE

AL, CN, NO, Candiolo,TO-CdS, TO-Irmet (2)

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BA, BR, LE, S.G.Rotondo, FG

PI, AR, FI, PO, Carrara

PG, Terni, Foligno

RM-tv (2), RM-ifo, LT, RM-Gem

SA, NA-Pa, NA-SDN (3), AV,Na-Fed II

Rionero, PZ

78 PET Scanner F^{18} phantom (93%)
4 PET Scanner Not qualified (5%)
2 PET Scanner CTQ ongoing (2%)

CA-bi, CA-bu

CZ,RC

CT,CT-gn, ME, PA, PA-Mad(2), Cefalù, ME-Papardo

Thanks for the attention