

DATA CENTER

After 14 years:

Raymond Omollo - Kampala, UG

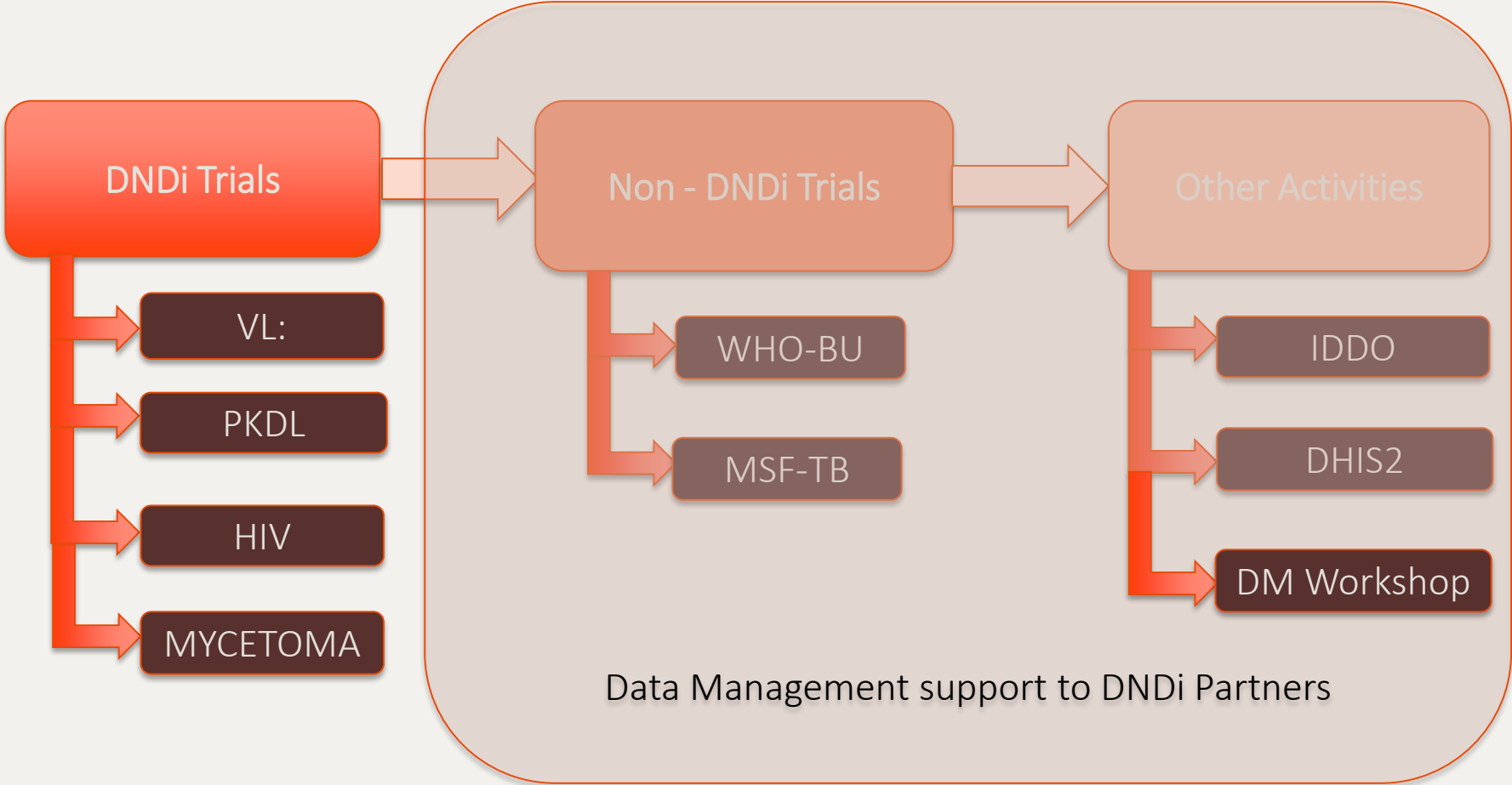
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Background:

- Set up in 2004 to address one of the key objectives on capacity building with a focus on:
 - Data Management and
 - Statistical Analysis
- Coincided with the beginning of the 1st Clinical Trial on VL in eastern Africa
- Initially had 2 staff and currently at 11
 - Working closely with consultants

DC Activities




Achievements

- Trials: both internal & external
- Others: DHIS2, IDDO
- Innovations: offline OC, QMSPlus
- Workshops & Conferences
 - Data Management: OpenClinica, Data Sharing
 - Statistics: ISCB

 OPEN ACCESS  PEER-REVIEWED

RESEARCH ARTICLE

Systematic review of clinical trials assessing the therapeutic efficacy of visceral leishmaniasis treatments: A first step to assess the feasibility of establishing an individual patient data sharing platform

Jacob T. Bush, Monique Wasunna, Fabiana Alves, Jorge Alvar, Piero L. Olliaro, Michael Otieno, Carol Hopkins Sibley, Nathalie Strub Wourgaft , Philippe J. Guerin 

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Achievements Cont'd

- Online Query Resolutions
 - Activated for PM/MF and PKDL trials
 - Shorter query resolution turnaround time has been realised.
- CDISC standards for VL
 - DC is collaborating with IDDO is developing CDISC standards for VL
 - Development of Generic VL CRF's is ongoing based on CDISC standards

Challenges:

- Internal:
 - Buy-in (case of WHO & MSF)
 - Resources constraints
- External: limited disease scope
- Reliance on open source DM Tools
 - **Merits of open source**
 - Affordable
 - Capacity building due to active community
 - **Challenges of open source**
 - Limited features compared to proprietary tools
 - Validation burden borne by the user

Future

- Secondary analysis in VL: (*potential for other disease areas*)
 - Time to haematological parameters improvement in Visceral Leishmaniasis: a marker of response and relapse
 - The Changing face of Visceral Leishmaniasis in Eastern Africa
 - Cardiotoxicity related to treatment of VL patients in Eastern Africa
 - Time to relapse and predisposing factors among VL patients

Future:

- EDC:
 - We can no-longer continue to operate the way we do.
 - Only perform highly specialised functions at the DC
- Open Access:
 - Data sharing
 - Include it as part of all future protocols
- Business case:
 - DC as a CRO/semi-autonomous unit within the organization (how about incubation?)



Thank you....
Any Questions?

DNDi

Drugs for Neglected Diseases *initiative*