Raising Disease Awareness and Improving Patient Care in Russia: Examples of Real-world Data (RWD) Generation Initiatives in Classic Hodgkin Lymphoma (cHL), Systemic Anaplastic Large Cell Lymphoma (sALCL)and Inflammatory Bowel Disease (IBD)

November 7th, 2019

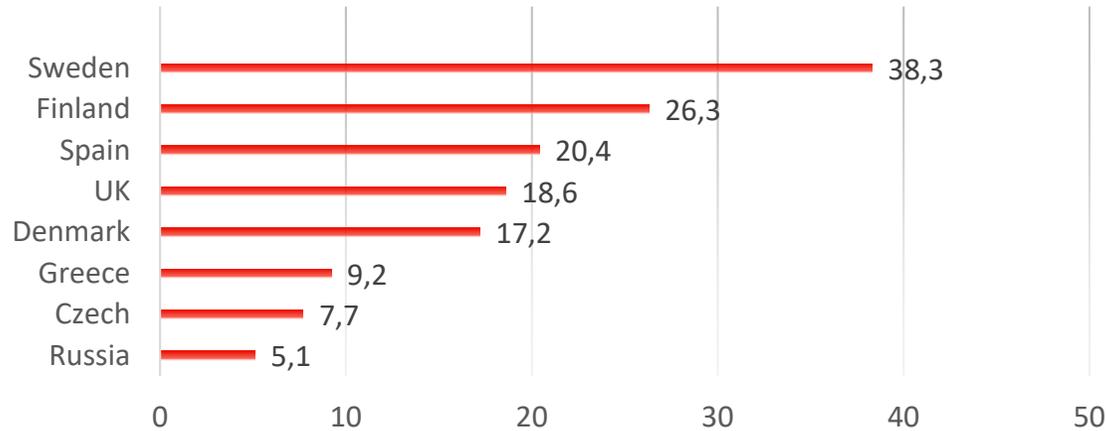Maria Leer, Head of Medical Projects Group
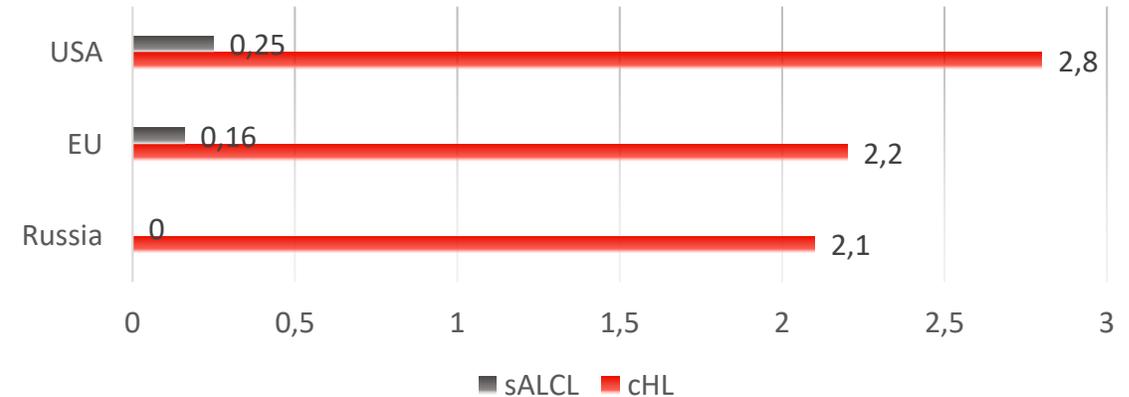
Medical Department

Takeda Russia

Background
IBD & cHL/sALCL – Situation in Russia
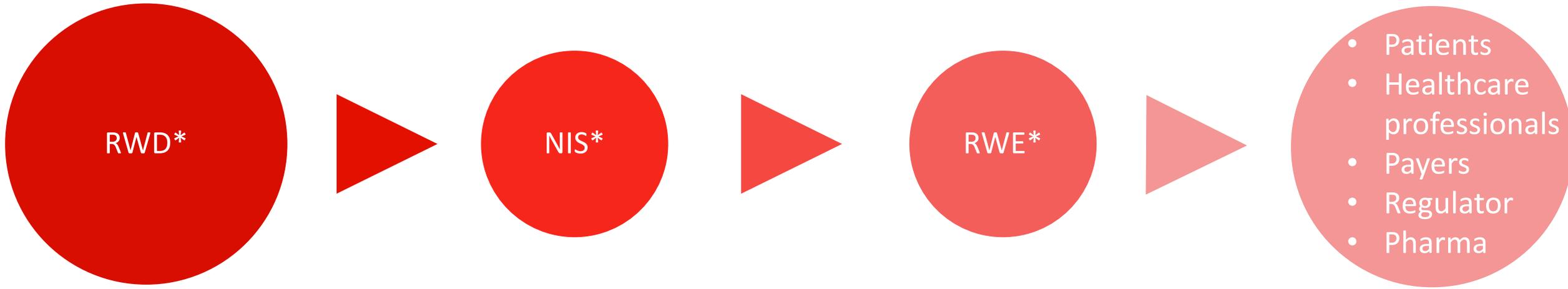

NUMBER OF IBD CASES PER 100 000 POPULATION PER YEAR

- Sweden: 38,3
- Finland: 26,3
- Spain: 20,4
- UK: 18,6
- Denmark: 17,2
- Greece: 9,2
- Czech: 7,7
- Russia: 5,1

NUMBER OF CHL/SALCL CASES PER 100 000 POPULATION PER YEAR

- USA: sALCL 0,25 | cHL 2,8
- EU: sALCL 0,16 | cHL 2,2
- Russia: sALCL 0 | cHL 2,1

sALCL ■ cHL ■

- Dramatically low diagnostic rate
- Absence of national registry
- Absence of established patient journey/follow up
- Late initiation of biologics due to low awareness and limited access to innovative treatment

- Absence of regular cHL/sALCL disease registers
- Limited epidemiological data
- Limited data about treatment patterns and results of real world therapy
- Limited patient-level data – patient's outcomes, extent of disease (meaning the ALCL as well as HL) from the real clinical practice

Takeda Russia Aims

RWD* → NIS* → RWE* →
- Patients
- Healthcare professionals
- Payers
- Regulator
- Pharma

Generated evidences:
- Disease register;
- Established patient journey/follow up;
- Clarified treatment patterns;
- Clarified epidemiological data;
- Etc.

*RWD – Real world Data, NIS – Non-interventional study, RWE – Real World Evidence

Methods

- **INTENT** is an international, multicentre, disease registry aimed at evaluating disease control and treatment patterns in adult (≥18 years) patients diagnosed with moderate to severely active IBD in real-world clinical practice

- **KLIO** - is the largest national, multicenter disease registry in Russia aimed to collect information regarding the real-life practice of adult cHL and sALCL patients' treatment patterns and disease control in the Russian Federation (either newly diagnosed or confirmed diagnosis of cHL, or patients with relapsed/refractory cHL or sALCL)

https://www.clinicaltrials.gov/ct2/show/NCT03532932   https://www.clinicaltrials.gov/ct2/show/NCT03942263

INTENT - Study Design

Primary objective:

Collect RWD regarding the treatment patterns associated with biologics agents use or standard therapy in patients with moderate to severe Ulcerative Colitis (UC) and moderate to severe Crohn's Disease (CD).

Secondary objectives:

To analyse the epidemiology RWD (demographics, medical, and treatment histories);

To evaluate and describe the implementation and achievement of Treat-to-target (T2T) goals in real-world clinical practice;

To evaluate utilization of the following healthcare resources : hospitalizations, surgeries, disability determination and sick leave sheet.

A Study to Evaluate Disease Control and Treatment Pattern in Participants With Moderate to Severe Inflammatory Bowel Disease (IBD) in Real Life Practice

3 Countries (Russia, Kazakhstan, Belarus)

3000 patients (**1156** actual)

35 sites

The biggest IBD study in the region CIS

KLIO - Study Design

Primary objective:

To describe patterns of treatment used for cHL and sALCL in real world setting.

Secondary objectives:

To describe long-term treatment outcomes

To evaluate primary treatment outcomes

To describe patterns of using brentuximab vedotin in real world clinical practice

To evaluate demographic and clinical characteristics of patients

To describe usage of imaging tests (PET, CT, PET/CT, MRI, ultrasound) in diagnostic, treatment approaches and evaluation of response

To evaluate healthcare resources utilization (HCRU) for patients with cHL or sALCL.

A Study to Describe Treatment Patterns and Disease Control in Participants With cHL and sALCL in Routine Clinical Practice in the Russian Federation
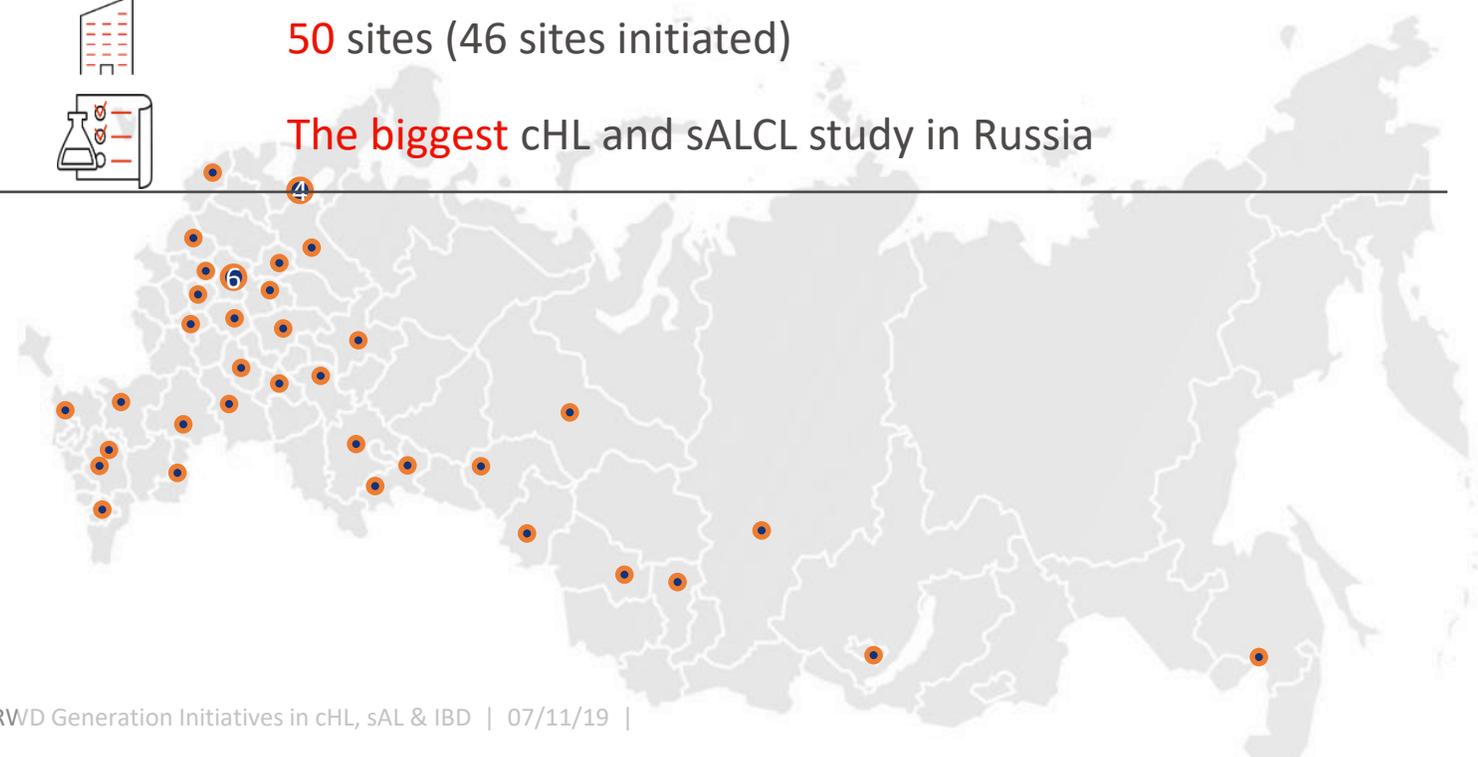
1 Countries (Russia)

3000 patients (498 actual)

50 sites (46 sites initiated)

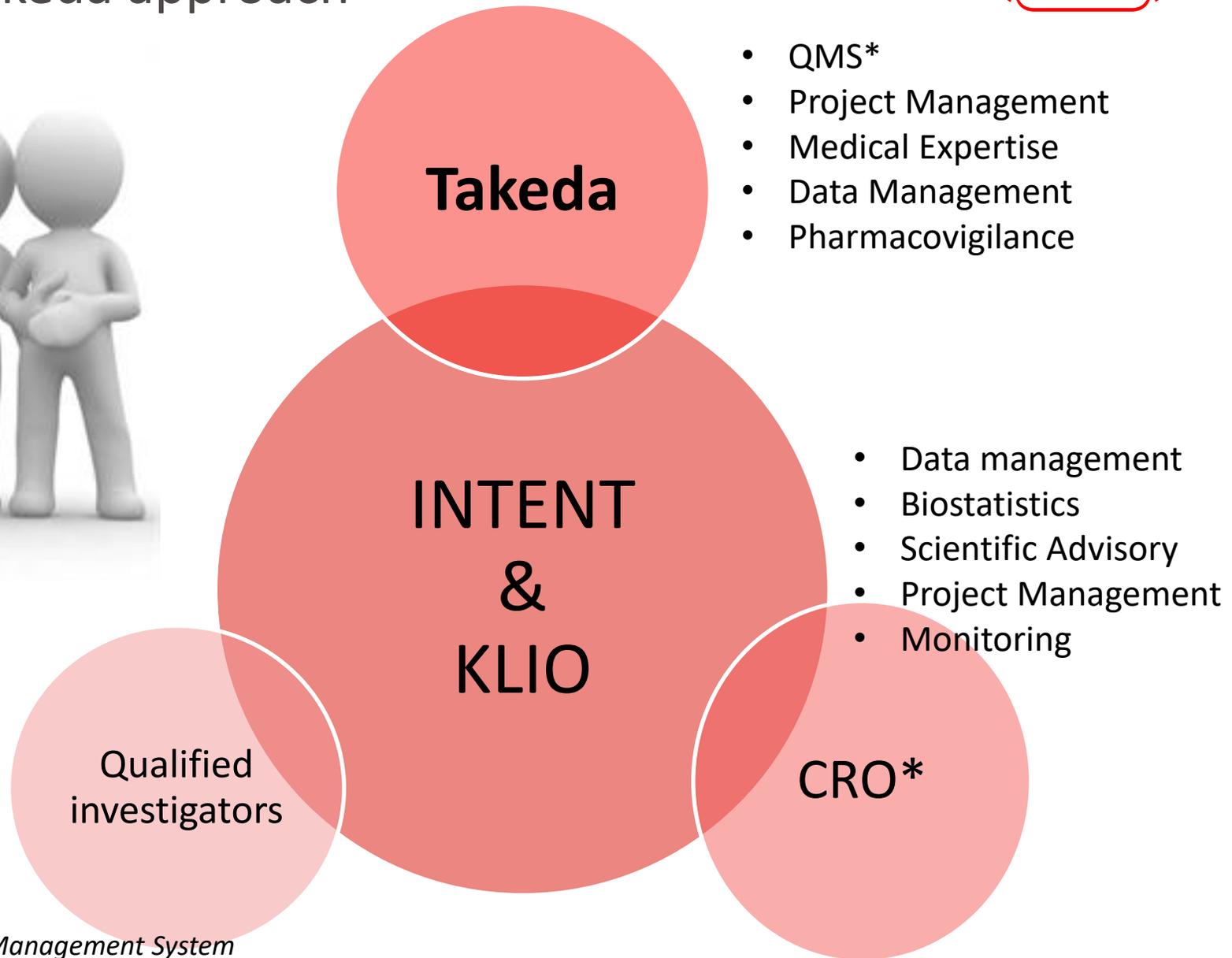The biggest cHL and sALCL study in Russia

Limitations

There are limitations in the evidence generated from disease registries that need to be considered. Firstly, diagnosis criteria, treatment assessments and outcomes may not be uniform and thus, there is potential for selection bias. Data are generally not verified and there may be a lack of complete data and follow-up information available for all patients. In addition, there may be limitations in the utilization of the evidence generated – for example, the infrastructure for health technology appraisal in Russia-CIS is still evolving and insights informing on the optimal patient journey and diagnostics may not always be possible to implement given local budgetary constraints.

Evidences high QUALITY - Takeda approach

High professionals
+
Established Quality
Management System
=
Evidences high QUALITY

Takeda

- QMS*
- Project Management
- Medical Expertise
- Data Management
- Pharmacovigilance

INTENT & KLIO

- Data management
- Biostatistics
- Scientific Advisory
- Project Management
- Monitoring

Qualified investigators

CRO*

*CRO – Clinical research organization, QMS – Quality Management System

Conclusion

- **Study results will enrich the scientific data on these nosologies**

Data will be used as supplementary material for regulatory affairs/payers

Study results dissemination will increase HCPs' awareness and facilitate drug access to the right patients at the right time.

Pharmaceutical companies are playing an ever-increasing role in the generation of real-world evidence (RWE) to raise awareness of the disease landscape

Evidence generated from local clinical practice will help to inform decision-making for health care professionals (HCPs), payers, improve disease diagnosis, access to innovative treatments and long-term outcomes in patients in Russia-CIS

Better Health, Brighter Future

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