

COA overview of the availability of instruments in Chinese for Chinese drug development

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Background

➤ A review was needed to determine the availability of COA instruments in Chinese markets. We focused on areas with high COA use – list Therapeutic areas for now and checked ePROVIDE database for the availability of Chinese instruments. ePROVIDE searches include Therapeutic areas, Therapeutic indications, Acronym of the questionnaires (PROQOLID™ content results, Full name of the questionnaires (PROQOLID™ content results), Brand name and INN of a drug (PROLABELS™ content results), and Title of guidance (PROINSIGHT™ content results).

Methods

➤ The diseases covered for each instrument are; Oncology, Endocrine metabolism, Rheumatology, Dermatology, Psoriasis, Irritable Bowel Syndrome IBS or IBD, Ankylosing spondylitis, and Neurology. Translations available for each disease area are kept in mind, prior selection of PRO instruments. Only those PRO instruments are selected that have translations into Chinese (traditional or simplified). Instruments are selected to measure different aspects of the disease area. For example, health quality of life, side effects, signs and symptoms, activities of daily living, utility, Psychological functioning, Patient satisfaction, and Physical functioning.

Age group for instruments selected is the 18+ Adult population. The Pediatrics PRO design area is very specific and is not covered in this paper.

Results

➤ A total of 193 instruments were identified from all the selected under-recognized disease areas: Oncology (102), Endocrine metabolism (34), Rheumatology (24), Dermatology (9), Psoriasis (6), Irritable Bowel Syndrome (8) IBS or IBD (8), Ankylosing spondylitis (7), and Neurology (3). And concepts of interest include; Quality of life instruments (94), Side effects (1), Signs and symptoms (58), activities of daily living (4), utility (6), Psychological functioning (14), Patient satisfaction (3), and Physical functioning (4).

Conclusions

➤ Several COA and PRO instruments are available for the Chinese market, further use in drug development and suitability for Chinese regulatory opinion is still to be determined. There are many instruments, and we can do lots of work in China already.

REFERENCES
ePROVIDE database.

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Table 1: Table showing names of some of the instruments selected under each disease area.

Disease area	Name of the instruments
Oncology	EORTC European Organization for Research and Treatment of Cancer (EORTC QLQ-C30); Patient-Reported Outcomes Measurement Information System® Physical Function in Oncology (PROMIS® Physical Function in Oncology); Functional Assessment of Cancer Therapy - General (FACT-G); Patient-Reported Outcomes – Common Terminology Criteria for Adverse Events (PRO-CTCAE); Patient-Reported Outcomes – Common Terminology Criteria for Adverse Events (PRO-CTCAE), MD Anderson Symptom Inventory - Traditional Chinese Medicine Module (MDASI-TCM); Functional Assessment of Chronic Illness Therapy - Fatigue Scale (FACIT-Fatigue).
Endocrine Metabolism	Functional Assessment of Cancer Therapy-Endocrine Subscale (FACT-ES); Summary of Diabetes Self-Care Activities (SDSCA); Diabetes Impact Measurement Scales (DIMS); Ferrans and Powers Quality of Life Index (QLI); Diabetes Quality of Life measure (DQOL); Hypoparathyroidism Patient Experience Scale-Impact (HPES - Impact); Thyroid-specific patient reported outcome – 39-item (ThyPRO-39).
Rheumatology	Systemic Lupus Erythematosus-Specific Quality-Of-Life scale (SLEQOL); Rheumatology Attitudes Index (RAI); Brief Pain Inventory (BPI); MultiDimensional Health Assessment Questionnaire (MDHAQ); (HAQ-DI) The health assessment questionnaire (HAQ) disability index (DI), DAS-28 disease activity scores; Western Ontario and McMaster Universities Arthritis Index (WOMAC®).
Dermatology	Dermatology Life Quality Index (DLQI); Family Dermatology Life Quality Index (FDLQI); Patient-Oriented Eczema Measure (POEM); Eczema Area and Severity Index (EASI); Scoring in Atopic Dermatitis (SCORAD); Nottingham Eczema Severity Score (NESS); Atopic Dermatitis Control Tool (ADCT).
Psoriasis	Psoriasis Symptom Scale (PSS); Psoriasis Disability Index (PDI); Psoriasis Signs and Symptoms Diary (PSSD); Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI:PSO); Physician's Global Assessment Scale or Investigator's Global Assessment Scale including Psoriasis Global Assessment (PGA-IGA).
Irritable Bowel Syndrome IBS or IBD	Inflammatory Bowel Disease Questionnaire (IBDQ); Irritable Bowel Syndrome - Quality Of Life (IBS-QOL); Short Health Scale (SHS); Outcome Rating Scale (ORS) (Generic); Pelvic Organ Prolapse Distress Inventory (POPDI); Pelvic Organ Prolapse Impact Questionnaire (POPIQ); Mini Nutritional Assessment - Original version (Full MNA®); Toronto IBD Global Endoscopic Reporting Score (TIGER Score).
Ankylosing spondylitis	Bath Ankylosing Spondylitis Metrology Index (BASMI); Bath Ankylosing Spondylitis Disease Activity Index (BASDAI); Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL); Bath Ankylosing Spondylitis Functional Index (BASFI); Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S); Health Assessment Questionnaire (HAQ).
Neurology	Michigan Neuropathy Screening Instrument (MNSI); Multiple Sclerosis Impact Scale (MSIS-29); Alzheimer's Disease Assessment Scale, Cognitive part (ADAS-COG).

Figure 1: Pie chart showing percentage of instrument selected under each disease area

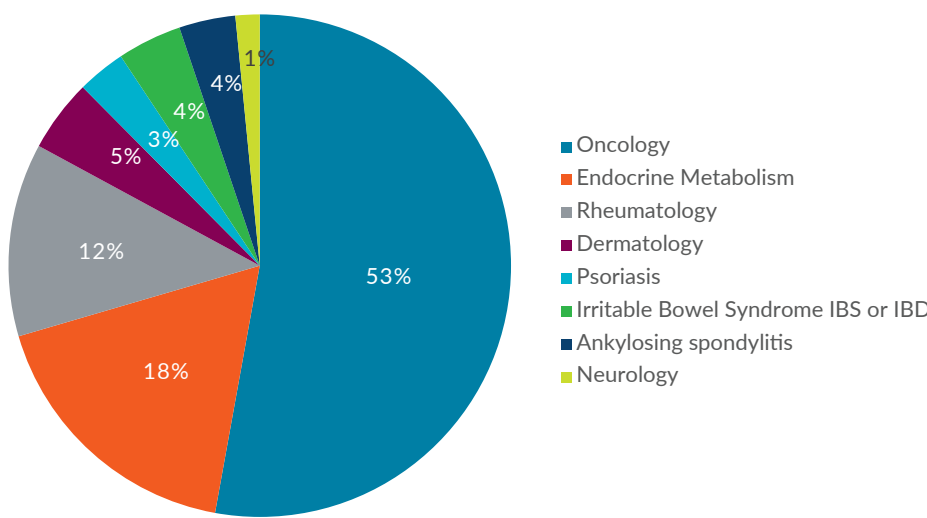
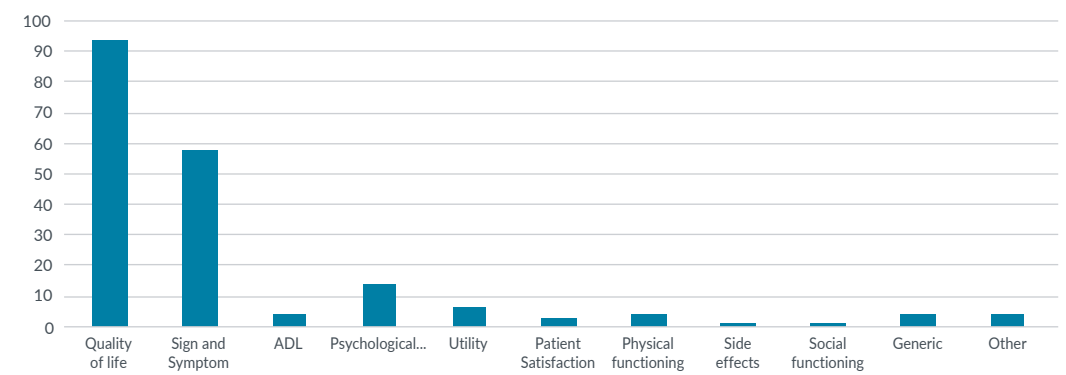


Figure 2: Graph showing types of instruments under selected disease area



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