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# Minimum requirements for establishment of an outcome registry

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# *Introduction*

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- Registry Fundamentals
  - Standardization
  - Quality assurance
  - Funding
  - Outcome
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- Database/collection of patient records
    - Clinical and lab data; day +100 and beyond
      - Trends
    - Transplant/Tx, toxicity and complications
      - Source of Tx, Conditioning, TRM
    - Follow up info
      - Survival/outcome analysis
  - Generally – electronic/online database
  - National outcome registry - centralizes country data to avoid redundancy
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# *Benefits of outcome registry*

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- Enhancing gaps in knowledge
  - Monitoring transplant trends/outcomes
    - For prompt attention; Res projects using registry data
  - Advocating for health care
    - Small investment → ↑ survival & ↓ complications
  - Resource Allocation – priority setting
    - Identifying needs & prioritizing for successful outcome
  - Serving as a distribution mechanism
    - Trends, patterns, outcome of drugs/regimens
  - Facilitating establishment of communication network
    - Information, education materials, notices for HSCT patients
  - Ensuring better global data
    - Advocating for improving care for world's HSCST population
  - Identifying population
    - Collaboration to study important regional issues
  - Synchronization across registries
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# *Principles of data collection*

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## ■ **Accuracy:**

- Policy decisions
- Bad data → bad policy decisions/lack of credibility

## ■ **Simplicity:**

- To reduce the number of errors and fatigue on those collecting the data

## ■ **Completeness:**

- A registry needs all the data – missing data reduces accuracy and data quality
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# *Minimum requirements*

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- Data collection
    - What do we want to know? Why do we want to know it?
  - Personnel/Staffing
  - Regulations/SOPS/IPPS
  - Data management/collection/storage
  - Communication
    - Center→Country→Region→World
  - Quality assurance
  - Funding
  - Data utilization/Sharing/Publications
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# *Personnel/Staffing*

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- Qualified, trained personnel
  - Use of effective registry tools/software
    - Collection, management and analysis
    - F/U mechanism
    - Effective communication
  - HSCT background/skills
    - Staging, grading, toxicity etc.
  - Documentation
    - Comprehensive
  - Understanding international guidelines and standards
  - Work load/proportionality
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# *Regulations*

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- By-laws
  - Data transfer agreements
  - Accreditation
    - JACIE
    - FACT
  - IRB
    - Local regulatory authorities in each country
    - Wide variation in ethical committees
    - Consenting issues
    - CIRB!
  - Privacy and Confidentiality
    - Unique identifier for pts - to avoid duplication
      - EMBMT Center #: Country code—city code—Ctr Number
      - WBMT Unique Global Transplant Center Number (GTCN):
        - Exclusive EBMT member GTCN 00383-00000-000000
        - EBMT and CIBMTR member GTCN 00292-00345-000000
        - EBMT, CIBMTR and APBMT member GTCN 00195-03456-000120
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# *Data collection*

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- EMR
    - EMR vs. traditional med records
      - Effective MR/Labs/path interfacing
  - Standardized registry software
    - Need for quality software
    - User friendly, reliable, validated, compatible and universally acceptable
      - FormsNet3/PROMISE/AGNIS/TRUMP/STEMSOFT/Others
      - Global registry by WBMT?
  - Redundancy in data collection
    - Reporting to several international registries
      - Harmonized forms/CRFs
  - Accuracy, integrity
    - Registry management/Data Monitoring Committee (DMC)
    - Quality control/internal & external audits/monitoring
  - QI/PI
    - Advanced survey forms; data collection and f/u mechanism
    - Need to secure timeline for f/u (day 100, 6 months, 1 yr, etc.)
  - Cross training of data managers
    - Continuous education & training, multi-disciplinary approach
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# *Communication*

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- Language barriers
    - Some countries under colonial rules
      - French vs. English speakers
    - Cultural, social and economical heterogeneity
      - Variety of languages/dialects
      - Regional differences
  - Cultural sensitivities
    - QOL forms
      - Limitations
      - Socio-cultural aspects
  - Queries
  - Reporting
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# *Quality assurance*

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## ■ Standardization

- Establishing accreditation standards
- Unification of HSCT registries
- Universal guidelines for different indicators
  - Lab units
  - Toxicity criteria (Berman, CTC, WHO)
  - GVHD definition and response criteria (NIH vs. others)
  - Performance status (KPS, ECOG)

## ■ Uniform QM standards with JACIE/FACT

- Good registry practice
- Accuracy, integrity, reliability, transparency

## ■ Implications/outcomes of registry data quality

- Inconsistency and fragmentation
  - Need to review/update registry CRFs/database annually
    - New variables, targets/markers, staging/grading (AJCC 8.0)
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# *Data utilization/Publications*

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- Sharing the data
    - Maximum utilization
    - Overlapping registries/multiple databases
    - Integration/interoperability
  - CIBMTR/EBMT data utilization
    - Limited! Need to secure complete data retrieval
    - EMBMT: Full access to all data centers
      - Harmonized registry forms
      - Encompassing MED-A and Pre-TED forms
        - Uniformity
        - Standardization
        - Validity and homogeneity
  - Authorship guidelines by the registry
    - # transplants
    - Contribution
    - Participation
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# *Essential elements*

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## **Patient**

### *Identification*

- Personal ID # (UPIN/Nat'l ID/SS)

### *Demographics*

- Gender
- Place of birth
- Marital status
- Age at Dx
- Nationality
- Occupation and industry
- Country of birth

## **Tumor and its investigations**

- Diagnosis
- Method/Date of Dx
- Clinical extent of dis pre-treatment
- Surg/path extent of dis pre-treatment
- Ch deletions/receptors/biomarkers
- Stage/Grade
- Site(s) of distant mets
- Donor type

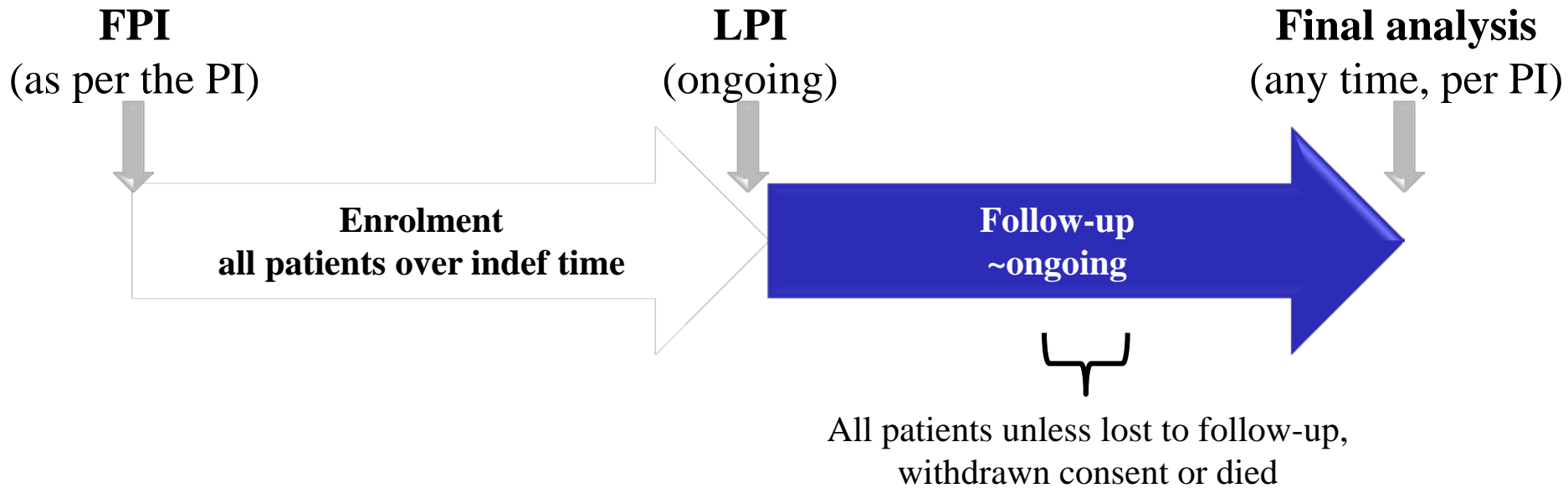
## **Treatment**

- Initial treatment/transplant
- Engraftment
- GVHD
- F/U-systematically
  - Response evaluation
  - Disease status post transplant
- Date of last contact
- Status at last contact (alive, dead, unk)
- Date of death
- Cause of death
- Place of death

## **Outcome/Survival analysis:**

- Short and long term F/U
  - Progression-free survival
  - Overall survival
  - Overall response rate
  - Clinical benefit rate
  - Duration of response
  - Time to response
  - Quality of life outcome
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# *Patient follow-up on Registry*



## **Final/Interim analysis:**

The periodic/interim analysis: at the discretion of the PI

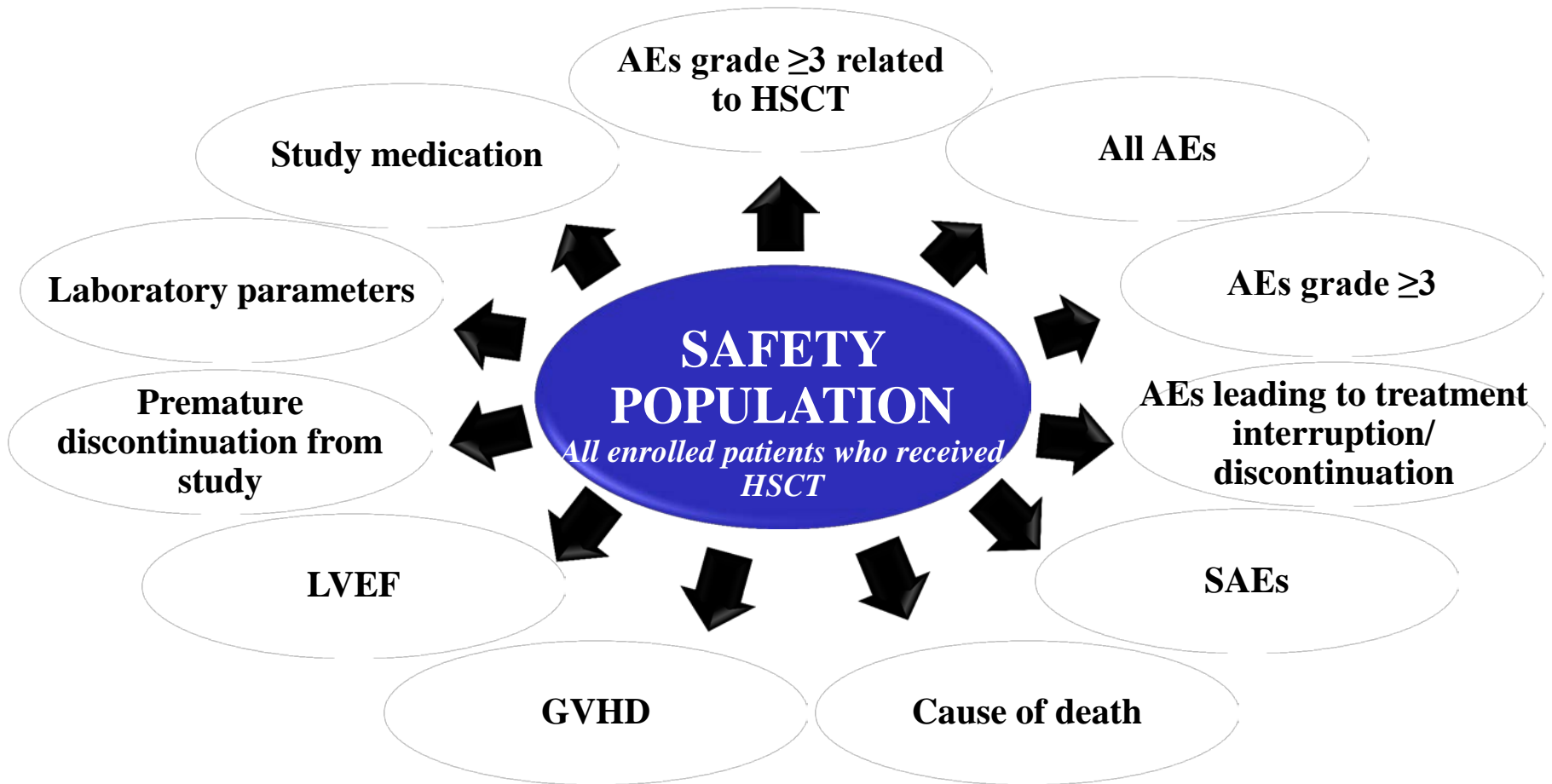
## **Options for the PI:**

Flexibility/wide variety of sub-groups/Multiple studies

Historic controls

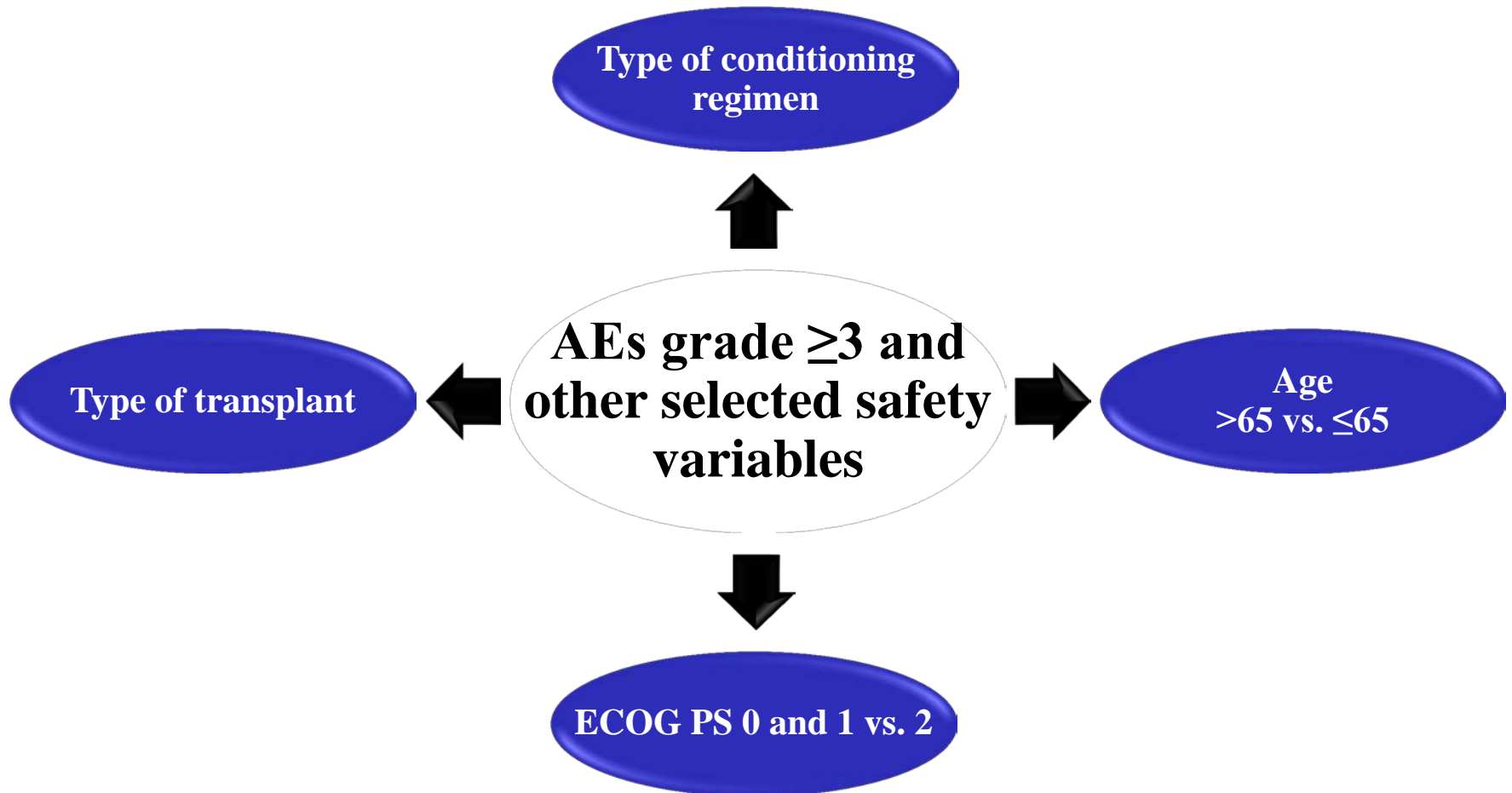
safety and efficacy data

# Safety variables



# *Subgroup analyses*

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# *Summary*

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- Data Quality is the foundation of outcome registries
  - Registries impact clinical decisions
  - Documentation is the key
    - If it is not documented, it did not happen!
  - Communication! Teamwork
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# *Questions?*

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